# A CLINICAL STUDY OF *SALSARADI GANA BHAWIT HARITAKI* IN THE MANAGEMENT OF *STHOOLA PRAMEHI* (DIABETES MELLITUS TYPE-2)

## Author - DR.BHAGYASHREE VALVI[1] , PROF. DR. SURENDRA A . SONI[2]

1.PG Scholar, Department of Kayachikitsa, Government Akhandanand Ayurveda College and Hospital Ahmedabad.

2.HOD, Department of Kayachikitsa ,Government Akhandanand Ayurveda College   and Hospital   Ahmedabad.

**Abstract:**

Various Acharyas have mentioned that the Bhawana of Salsaradi Gana is Madhumeha-hara properties. Hence study is planned to evaluate the effect of Salsaradi *Gana Bhawit Haritaki* and *Vijayasaradi Kwath* in the management of *Sthoola Pramehi* 50 Patients having classical symptomatology of *Sthoola Pramehi* have been selected from the O.P.D. of Govt. Ayurvedic College & Hospital, Ahmedabad) and divided into two groups. Results of the study show that *Salsaradi Gana bhavita Haritaki* significantly decreased blood glucose levels in diabetic patients in both groups. According to a study, *Salsaradi Gana bhavita Haritaki* with *Vijayasaradi kwath* has better results.

**Keywords -** Diabetes mellitus, Sthoola Pramehi, Salsaradi Gana Bhavit Haritaki, Vijayasaradi Kwath

## Introduction

Acharya Sushruta has mainly described Salsaradi Gana in sutra sthana 37th chapter. Here he has given a list of 23 plants that make the Salsaradi Gana. Describing the properties of this Gana, he says that Salsaradi Gana possesses Kapha and Medoshoshana properties and is useful in Kushtha (skin disease), Prameha (diabetes), and Pandu rog (anaemia). Thus, it becomes commonly used in the Kapha, Pitta stage of Samprapti of madhumeha where there is Kleda Vriddhi.

In *Ayurveda Acharya Charaka* has mentioned two types of *Prameha* According to *Bala* of *Rogi* one is *Sthoola* (obese) and the other is *Krish* (Asthenic) in *Chikitsa Sthana. Acharya Sushruta* has also mentioned *Apathya Nimittaj Prameha* whose Signs and Symptoms can be correlated with *Sthoola Pramehi.* The same type of classification can be seen in   modern science as

Obese (NIDDM) and Non-obese (IDDM) types. *Sthoola Pramehi* Symptoms like *Prabhuta-Mutrata* and *Pipasa* can be equated with three cardinal symptoms of type-II Diabetes mellitus viz polyuria, polyphagia, and polydipsia.

The most important is the presence of sugar in the urine (*Mutra Madhuryata)* which is mentioned as *Mutre Abhidhavanti Pippalika. Acharya Sushruta* has mentioned *Sthaulya* leading to *Prameha*[8]. Allopathy science also indicates Obesity as a major risk factor for type-II Diabetes Mellitus. In *Grahani Chikitsa, Charaka* has mentioned *Ajirna* due to *Vishamashana* and *Adhyashana* and that *Ajirna* leads to the formation of *Ama* further *Sansrujya* with *Kapha Dosha* and

producing *Prameha Roga*. So here *Ajirna* indicates that *Prameha* has Metabolic disorder.

Diabetes can be divided into 3 categories.1) *Sthoola Pramehi* 2) *Kulaja Prameha Avarana Janita Prameha*. The main *Dosha* in diabetes is *Kapha* and the main *Dhatu* is *Meda*. The patients who don't have a family history but have a sequence of *Nidanas* excessively like intake of fast food, non-veg food, wine/beer, anabolic steroids, irregular lifestyle, and irregular exercise are Closer to *Avarana-Janita-Madhumeha* due to *Dhtvagnimandhya* and *Ojas Kshaya* condition. *Ayurveda* is capable of regenerating the Langerhans cells based on the *Dhatugatatva* principle and its management though primarily not forced on the revival of Langerhans Cells.

## AIMS

➢ To compare the efficacy of *Salsaradi Gana Bhavit Haritaki* and *Vijaysaradi Kwatha* in the management of *Sthoola Pramehi.*

## OBJECTIVES

➢ To evaluate the efficacy of the trail drug *Salsaradi Gana Bhavit Haritaki* in the management of *Sthoola Pramehi.*

➢ To evaluate the safety of trail drug S*alsaradi Gana Bhavit Haritaki* in the management of *Sthoola Pramehi*.

## EXPECTED OUTCOMES

**Primary Outcome**: Improvement in laboratory parameters as well as signs and symptoms of *Sthoola Pramehi* (Type – II Diabetes Mellitus).

**Secondary outcome***:* It is expected that the drug will break /eradicate the root cause of the disease leading to a permanent cure of Diabetes in *Sthoola Pramehi* the installing *Rasayan* Properties.

## Plan of study

## INCLUSION CRITERIA

➢ Patients of either sex in the age group of above 18 years and below 65 years.

➢ Classical signs and symptoms of Prameha.

➢ Fasting plasma glucose ≤ 200 mg/dl, post-prandial glucose level ≤ 300 mg/dl.

➢ Both insulin-dependent and non-insulin-dependent Type – II Diabetes Mellitus patients will be included.

➢ Both newly diagnosed patients on allopathic treatment will be included in this study. The

dose of Modern Medicine will be adjusted and tapered during the period of trial as needed.

➢ Patients having BMI (Body Mass Index) ≥ 25 and ≤ 35 will be taken for the study.

### EXCLUSION CRITERIA

➢ The patient's age is below 18 years and above 65 years.

➢ Fasting plasma glucose level >200 mg/dl & Postprandial glucose level >300 mg/dl will be excluded

➢ Patients having any other malignancies or any other systemic/ serious illness.

➢ Patients with diabetic wounds/ulcers

➢ Patients of Diabetes mellitus Type – 1 (Juvenile Diabetes)

➢ Patients having acute & serious complications of Type – 2 Diabetes Mellitus

➢ Chronic Pancreatitis, Ketoacidosis, and Parkinson's disease.

➢ Patients with other metabolic and endocrinal disorders.

➢ Patients have uncontrolled blood sugar.

➢ Patients with Coronary artery disease, Peripheral vascular disease & cerebrovascular disease

➢ Patients having a history of any major complications of Diabetes like Nephropathy, Retinopathy, Diabetic Foot, etc.

➢ Pregnant women

➢ Otherwhere chronicles like STD, Tuberculosis, etc.

➢ BMI <25 and > 35 will be excluded.

### Grouping

|  | Group A | Group B |
| --- | --- | --- |
| **Drug** | *Salasaradi Gana Bhavit Haritaki* | *Vijaysaradi Kwath* |
| **Form** | *Churna* | *Kwath* |
| **Dose (Ascending– Descending)** | 2.5 to 7 gm BD | 20 ml BD |
| **Mode of Administration** | Oral | Oral |
| **Time of Administration** | Early morning on an empty stomach and in the evening | Early morning on an empty stomach and in the evening |
| ***Sahapana / Anupana*** | Lukewarm water | Lukewarm water |
| **Duration** | 40 Days | 40 Days |
| **Follow up** | Every 15 Days | Every 15 Days |

### CRITERIA FOR ASSESSMENT

### SUBJECTIVE CRITERIA:

After completion of therapy, before and after treatment scores were assessed on the basis of specially prepared proforma containing detailed history and symptoms of the disease as per Ayurvedic texts and modern parameters.

**OBJECTIVE CRITERIA:**

Improvement in laboratory investigations like FBS, PPBS

**ADDITIONAL CRITERIA**

Assessment of changes/ Reduction in Drug dosage/Insulin dose taken by the patient.

**GRADATION OF SYMPTOMS**

*Prabhut Mutrata* **(Frequency of Urine)**

| 1 | 3-6 times per day, rarely at night | 0 |
|---|---|---|
| 2 | 6-9 times per day, 0-2 times per night | 1 |
| 3 | 9-12 times per day, 2-4 times per night | 2 |
| 4 | More than 12 times per day, more than 4 times per night | 3 |

*Avil Mutrata* **(Turbidity)**

| 1 | Crystal clear fluid | 0 |
|---|---|---|
| 2 | Faintly cloudy, smoky, or hazy with slight turbidity | 1 |
| 3 | Turbidity visible but newsprints easily read through test tube/Glass container | 2 |
| 4 | Newsprint is not easily read/seen through a test tube | 3 |

*Kshudha – Adhikya* **(Increased Appetite)**

| 1 | Normal | 0 |
|---|---|---|
| 2 | Slightly increased (1 meal extra with routine diet) | 1 |
| 3 | Moderately increased (2 extra meals with routine diet) | 2 |
| 4 | Markedly increased (3 extra meals with routine diet) | 3 |

*Pipasa – Adhikya* **(Increased Thirst)**

| 1 | Feeling of thirst (7-9 times/24 hours) & relieved by drinking water | 0 |
|---|---|---|
| 2 | Mild increase in thirst (9-11 times/24 hours) & relieved by drinking water | 1 |
| 3 | The moderate increase in thirst (11-13 times/24 hours) is not relieved by drinking water | 2 |

| 4 | Feeling of severe thirst (>13 times/24 hours) not relieved by drinking water | 3 |
|---|---|---|

### Kara – Pada – Tala Daha

| 1 | No Daha | 0 |
|---|---|---|
| 2 | Hasta-Pada-Tala Daha occasionally, mild/bearable | 1 |
| 3 | Hasta-Pada-Tala Daha is continuous but bearable, not severe | 2 |
| 4 | Hasta-Pada-Tala Daha is continuous and severe | 3 |

### Kara – Pada Tala Suptata

| 1 | No Suptata | 0 |
|---|---|---|
| 2 | Kara-Pada Suptata temporarily/Occasionally & mild | 1 |
| 3 | Kara-Pada Suptata is frequent but bearable, not severe | 2 |
| 4 | Kara-Pada Suptata continuous & severe | 3 |

### Swedadhikya (Increased perspiration)

| 1 | No sweating | 0 |
|---|---|---|
| 2 | Increased sweating after moderate work and movement | 1 |
| 3 | Increased sweating after little work and movement (stepping ladder etc.) | 2 |
| 4 | Increased sweating even at rest & normal weather | 3 |

### Gala Talu Shosha (Dryness of mouth and oral cavity)

| 1 | Absent | 0 |
|---|---|---|
| 2 | Present | 1 |

### Daurbalya (General Debility)

| 1 | No Daurbalaya | 0 |
|---|---|---|
| 2 | Not able to perform strenuous activity. | 1 |
| 3 | Not able to perform moderate activity. | 2 |
| 4 | Even mild activity cannot be performed. | 3 |

### Sharma (Fatigue)

| 1 | No fatigue | 0 |
|---|---|---|
| 2 | Fatigue occasionally on doing heavy work | 1 |
| 3 | In carrying out routine work | 2 |
| 4 | Even without doing work | 3 |

### Angagandha (Bad Odour)

| 1 | No Odour | 0 |
|---|---|---|
| 2 | Bad Odour but offensive | 1 |
| 3 | Strong Odour but can be lessened using deodorants or perfumes | 2 |
| 4 | Very strong Odour even after using fragrances (use of deodorants or perfumes) | 3 |

*Tandra* **(Drowsiness)**

| 1 | No drowsiness | 0 |
|---|---|---|
| 2 | Mild/Slight drowsiness | 1 |
| 3 | Moderate drowsiness | 2 |
| 4 | Patients feel Excessive & Frequent drowsiness | 3 |

## CRITERIA FOR OVERALL ASSESSMENT

1) Markedly improved –75% to 99% improvement

2) Moderately improved -51% to 74% improvement

3) Mild improved- 25% to 50%

4) Unchanged - below 25%

❖ **STATISTICAL ANALYSIS OF DATA AND PRESENTATION OF RESULT**

▪ The information gathered based on observations is subject to statistical analysis.

▪ Signs and symptoms of Diabetes have been given various gradations as per the marking scheme. After completion of the course of treatment, the results were assessed based on differences in the score of signs and symptoms. The stage of the disease and overall improvement shall be taken into consideration while scoring.

▪ The Wilcoxon's Signed-Rank Test and Students paired 't' test was carried out to analyze the effect of individual therapy in both the groups. Students Unpaired 't' test has been applied to compare the effect of therapies between the groups. The results are interpreted at $P < 0.05$ and $P < 0.001$ significance levels.

**EFFECT OF THERAPIES ON SUBJECTIVE CRITERIA**

| Complaints | Group | Mean | | Mean diff. | % Relief | SD | SE | W | P | S |
|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | | | | | | | |
| *Prabuta mutrata* | A | 2.36 | 0.36 | 2.00 | 84.74 | 0.64 | 0.09 | 325 | < 0.0001 | HS |
| | B | 2.04 | 0.44 | 1.60 | 78.43 | 0.816 | 0.163 | 276 | <0.0001 | HS |
| *Avilamutrata* | A | 2.24 | 0.44 | 1.80 | 80.35 | 0.776 | 0.152 | 300 | <0.0001 | HS |
| | B | 1.72 | 0.52 | 1.20 | 69.76 | 0.577 | 0.115 | 276 | <0.0001 | HS |
| *Kshudhadhikya* | A | 1.96 | 0.52 | 1.44 | 73.46 | 1.003 | 0.200 | 210 | <0.0001 | HS |
| | B | 2.00 | 0.72 | 1.28 | 64 | 0.541 | 0.108 | 300 | <0.0001 | HS |
| *Pipasadhikya* | A | 2.08 | 0.44 | 1.64 | 78.84 | 0.952 | 0.190 | 253 | <0.0001 | HS |
| | B | 2.20 | 0.72 | 1.48 | 67.27 | 0.509 | 0.102 | 325 | <0.0001 | HS |
| *Karapadataladaha* | A | 2.40 | 0.52 | 1.88 | 78.33 | 1.013 | 0.202 | 276 | <0.0001 | HS |
| | B | 2.36 | 0.96 | 1.40 | 59.32 | 0.500 | 0.100 | 325 | <0.0001 | HS |
| *Karapadatalasuptata* | A | 2.64 | 0.52 | 2.12 | 80.30 | 0.665 | 0.133 | 325 | <0.0001 | HS |
| | B | 2.16 | 0.80 | 1.36 | 62.96 | 0.700 | 0.140 | 276 | <0.0001 | HS |
| *Swedadhikya* | A | 2.36 | 0.44 | 1.92 | 81.35 | 0.862 | 0.172 | 300 | <0.0001 | HS |
| | B | 2.60 | 0.84 | 1.76 | 67.69 | 0.663 | 0.132 | 325 | <0.0001 | HS |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Nindradhikya* | A | 1.64 | 0.40 | 1.240 | 75.60 | 0.969 | 0.193 | 171 | <0.0001 | HS |
| | B | 1.84 | 0.60 | 1.24 | 67.39 | 0.830 | 0.166 | 231 | <0.0001 | HS |
| *Mutramadhurya* | A | 1.84 | 0.40 | 1.44 | 78.26 | 1.040 | 0.208 | 190 | <0.0001 | HS |
| | B | 1.96 | 0.48 | 1.48 | 75.91 | 0.653 | 0.130 | 276 | <0.0001 | HS |
| *Daurbalya* | A | 2.20 | 0.56 | 1.64 | 74.54 | 0.860 | 0.172 | 231 | <0.0001 | HS |
| | B | 2.24 | 0.64 | 1.60 | 71.42 | 0.577 | 0.115 | 300 | <0.0001 | HS |
| *Tandra* | A | 1.52 | 0.32 | 1.20 | 78.94 | 0.866 | 0.173 | 210 | <0.0001 | HS |
| | B | 1.92 | 0.56 | 1.36 | 70.83 | 0.637 | 0.127 | 276 | <0.0001 | HS |
| *Angagandha* | A | 2.28 | 0.32 | 1.96 | 85.96 | 0.888 | 0.177 | 276 | <0.0001 | HS |
| | B | 1.56 | 0.52 | 1.04 | 66.66 | 0.789 | 0.157 | 171 | <0.0001 | HS |
| *Gala-talu shosha* | A | 2.08 | 0.60 | 1.48 | 71.15 | 0.871 | 0.174 | 253 | <0.0001 | HS |
| | B | 2.08 | 0.56 | 1.52 | 73.07 | 0.714 | 0.142 | 300 | <0.0001 | HS |

## EFFECT OF THERAPY ON OBJECTIVE CRITERIA

| Group | Mean | | Mean Diff | Relief | SD | SE | T | P | S |
|---|---|---|---|---|---|---|---|---|---|
| | BT | AT | | | | | | | |

|  |  |  |  |  | **%** |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|
| **FBS** | **A** | 173.49 | 121.2 | 52.49 | 30.25 | 43.24 | 4.324 | 12.13 | <0.0001 | HS |
|  | **B** | 173.14 | 136.36 | 36.78 | 21.24 | 39.69 | 7.94 | 4.63 | 0.0001 | HS |
| **PPBS** | **A** | 265.35 | 167.18 | 98.17 | 37.81 | 30.52 | 7.40 | 13.26 | <0.0001 | HS |
|  | **B** | 278.98 | 191.16 | 87.82 | 31.47 | 40.85 | 8.17 | 10.74 | <0.0001 | HS |

## COMPARISON OF EFFECT OF THERAPY ON SUBJECTIVE CRITERIA OF BOTH GROUPS

| Complaints | Group | Mean diff. | % Relief | SD | SE | U | P | S |
|---|---|---|---|---|---|---|---|---|
| *Prabuta mutrata* | A | 2.00 | 84.74 | 0.6455 | 0.1291 | 227.50 | 0.0487 | S |
|  | B | 1.60 | 78.43 | 0.8165 | 0.1633 |  |  |  |
| *Avilamutrata* | A | 1.80 | 80.35 | 0.7638 | 0.1528 | 164.50 | 0.0019 | VS |
|  | B | 1.20 | 69.76 | 0.5538 | 0.1108 |  |  |  |
| *Kshudhadhikya* | A | 1.44 | 73.46 | 1.003 | 0.2007 | 282.50 | 0.2812 | NS |
|  | B | 1.28 | 64 | 0.5416 | 0.1083 |  |  |  |
| *Pipasadhikya* | A | 1.64 | 78.84 | 0.5831 | 0.1166 | 221.50 | 0.0371 | S |
|  | B | 1.48 | 67.27 | 0.4583 | 0.0916 |  |  |  |
| *Karapadataladaha* | A | 1.88 | 78.33 | 1.013 | 0.2026 | 220.00 | 0.0356 | S |
|  | B | 1.40 | 59.32 | 0.500 | 0.1000 |  |  |  |
| *Karapadatalasuptata* | A | 2.12 | 80.30 | 0.6658 | 0.7000 | 146.50 | 0.0006 | HS |
|  | B | 1.36 | 62.96 | 0.1332 | 0.1400 |  |  |  |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Swedadhikya* | A | 1.92 | 81.35 | 0.8622 | 0.1724 | 261.50 | 0.3224 | NS |
| | B | 1.76 | 67.69 | 0.7483 | 0.1494 | | | NS |
| *Nindradhikya* | A | 1.240 | 75.60 | 0.9695 | 0.1939 | 309 | 0.9610 | NS |
| | B | 1.24 | 67.39 | 0.8307 | 0.1661 | | | |
| *Mutramadhurya* | A | 1.44 | 78.26 | 1.044 | 0.2088 | 307 | 0.4609 | NS |
| | B | 1.48 | 75.91 | 0.6532 | 0.1306 | | | |
| *Daurbalya* | A | 1.64 | 74.54 | 0.8602 | 0.1720 | 286 | 0.6069 | NS |
| | B | 1.60 | 71.42 | 0.5774 | 0.1155 | | | |
| *Tandra* | A | 1.20 | 78.94 | 0.8660 | 0.1732 | 268 | 0.1939 | S |
| | B | 1.36 | 70.83 | 0.6377 | 0.1275 | | | |
| *Angagandha* | A | 1.96 | 85.96 | 0.8888 | 0.1778 | 143 | 0.0010 | HS |
| | B | 1.04 | 66.66 | 0.7895 | 0.1579 | | | |
| *Gala-talu shosha* | A | 1.48 | 71.15 | 0.8718 | 0.1744 | 298 | 0.4879 | **NS** |
| | B | 1.52 | 73.07 | 0.7223 | 0.1474 | | | |

## Discussion

### Drug discussion

The drugs used in the present study were

### (A)*Salsaradi Gana Bhavit Haritaki*

❖ According to various *Nidanas* in the form of *Aaharaj* (*Gramya-Anupa Mamsa*, *Paya*, *Gudavaikruta*, Guru-*Snigdha-Abhshyandi,* etc..), *Viharaja* (*Asyasukham*, *Swapnasukham,* etc,) and *Manasika Nidanas* (*Chinta*, *Shoka*, *Udvega* etc.) leading to *Tridosha Prakopa* (especially *Kapha Dosha*),

(A)*Salsaradi Gana Bhavit Haritaki*

(B)*Vijasaradi with*

which in turn, cause *Medo Dusti* due to *Samana Guna* which leads to *Dhatvagnimadhya* and manifest *Madhumeha*. Therefore, drugs having *Kapha-Medo nashaka*, *Amapachana*, *Srotosodhana*, *Vatanulomana* & *Rasayana* properties had been selected.

- *Haritaki i*s mainly of *Kashaya Rasa, Ushna*, *Ruksa Guna*. It acts as *Kaphghna*, these qualities of *Haritaki* act as a cleanser and also improve digestion. Same as in Diabetes (*Prameha)* there is *Dusti* of *Medovaha Srotas* and *Dhatvagni*, especially *Mandya*. Hence there is a need for *Dravya* which is of *Usṇa, Rukṣa Gunas* with *Lekhan & Shoshan* properties to Cleanse the *Medovaha Stratos* and to increase the *Dhatvagni.*

- *Haritaki* processed in *Salsaradi Gana Dravya Kwath* 7 times to sharpen the action of *Haritaki* with *Rasayan* property. That's why this research plan has been designed as per *Rasayan Vidh*i with *Aarohi-Avarohi Krama* of the drug during the trial period.

- *Acharya Sushruta* describes *Salsaradi Gana* in *Dravya Sangrahaniya Addhyaya* of *Sutrasthana.* According to *Acharya Sushruta, Salsaradi Gana* possesses *Kapha–Medoshoshan* properties.

- Due to *Tikta, Kashaya, Katu Rasa, Ushna Virya, Ruksha Guna* of *Salsaradi gana bhavit Haritaki* acting as *Kapha-Medohara* and it might remove the *Avarana* caused by *Meda and Kapha* which increases the insulin

sensitivity by peripheral glucose utilization. *Tikta* rasa with its *Shoshana* and *Lekhana* properties, Cleans the *Srotas* (*Srotosodhana*) and increases *Rasayan* property basic cellular metabolism.

### (B)*Vijaysaradi Kwath*

- *Vijaysaradi Kwath* contains mainly *Tikta Kashaya Rasa* and has *Rukshana* properties *Tikta Rasa* has *Kledameda- vasa-majja-lasika Shoshana* properties and is known to be successfully used for the treatment of *Madhumeha. .*

- *Bahudrava Sleshma*, *Kleda,* and *Meda* are the main *Dushyas* of *Madhumeha* By *Upshoshana* properties of *Tikta & Kashaya* rasa & *Ruksha Guna* of *Vijayasaradi kwath, Bahudravata* will be reduced. Due to the above properties of this drug, good glycemic control is achieved.

- *Vijaysar* has significant importance in Ayurveda in managing diabetes and is also known as "The miracle cure for Diabetes" mainly due to its *Tikta* (bitter) nature. *Vijaysar* helps to manage blood sugar levels by preventing damage to pancreatic cells and promoting insulin secretion due to its antioxidant and anti-inflammatory activity.

### Prabhuta mutrata

Group A has shown 84.74% improvement in *Prabhutamutrata* while in group B 78.43% relief was found. In group A (p <0.0001) and group B (p<0.0001) statistically highly significant result was found but based on percentage *Salsaradi Gana bhavit Haritaki* was found to be more effective than *Vijayasaradi Kwath*. Both groups showed highly significant results in these symptoms, but still, group A *Salsaradi gana bhavit haritaki* showed better results percentage-wise.

*Mutrata* which increases due to the *Kaphaprakopa* which leads to *Kledavrudhi* throughout the body was reduced due to *Kledanirharan* properties of *Salsaradi gana bhavit haritaki*.

Polyuria is due to the osmotic diuresis caused by an increase in blood glucose level. *Bahu Drava Sleshama, Kleda & Meda* are the main *Dushyas* of *Prameha*. *Kledavahana* is a function of *Mutra* and due to this excessive *Kleda* is excreted through *Mutra* and as *Salsaradi gana* all drugs having *katu, Tikta Rasa, Laghu, Ruksha Gun*a but not decreased *haritaki guna* because of *yogavahi*. When *Haritaki is* processed in *salsaradi gan Dravya kwath* 7 times to sharpen the action of *haritaki.Haritaki* removed dosha through GIT due to *anulomana, Meda kleda lekhana* properties.

### Avila Mutrata

Group A showed 80.35% improvement in *Avilamutrata* while in group B 69.76% relief was found. In group A (p<0.0010) and group B (p<0.0001) statistically highly significant results were found but based on the percentage *Salasradi gana bhavit haritki* was found to be more effective than *Vijaysaradi kwath*.

Turbid urine is due to the excretion of metabolites of the body in the urine. *Vagbhata* emphasized that this turbidity of the urine is because of its amalgamation with the *Dhatus.Avil Mutrata . Avila mutrata removes through Meda-kleda shoshana Anulomana* properties of *Salsaradi Gana bhavit Haritaki* Due to *avarana bhedana*. Remove fat particles (Ketone bodies). *Haritaki* remove (*Sharira kleda*) dosha through GIT due to *anulomana, Meda- kleda lekhana* properties.

### Kshudhadhikya

Group A showed 73.46 % improvement in *Kshudhadhikya* while in group B 64% relief was found. In group A (p<0.0010) and group B (p<0.0001) statistically highly significant results were found but based on percentage *Salsaradi Gana bhavit Haritaki* was found to be more effective than *Vijayasaradi Kwath*.

Diabetes mellitus disrupts the body's ability to transfer glucose from food into energy. Intake of food causes glucose levels to rise without a corresponding increase in energy, which leads to a persistent sensation of hunger. Due to improper metabolism, *Meda Dhatu* and Atyagni which leads to *Kshudhadhikya* reduced markedly due to *Medohara a*nd *Samagni* action of  *Salsaradi gana Bhavit Haritaki*.

 *Kshudhadhikya* is produced due to aggravated *Vatadosha* due to the *Avarana* of *Meda* and *Mamsa*. *Avarana* of *Samana Vayu* is responsible for *Kshudhadhikya*. Both groups showed highly significant results in these symptoms, but still, group A, *Salsaradi gana bhavit haritaki* showed a better result percentagewise.

*Salsaradi gana bhavit haritaki* drug acted as *Medohara*, *Vata-Kapha Shamana,* and due to this, it destroys *Avarana* caused by *Meda* and *Kapha* Because of all drugs having *katu,tikta rasa*, *Ushna guna* opposite to *Kapha Dosha*. *Salsaradi gana bhavit haritaki Regulate Agni* and *Meda avarana bhedana* .

## Mutramadhurya

Group A has shown 78.26% improvement in *Mutramadhurya* while in group B 75.91% relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant result was found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath*.

 In *Salsaradi gana bhavit haritaki* most drugs have *Ushna, and Tikshna* properties They Act as *Srotoshodhna, Srotoprasadhana, and Vatanulomana*, therefore, they help  to reduce increased *Ama* and *Malotpatti* and decrease the excess of *Kleda* and relieve the symptom of *Mutramadhurya.*

## Pipasadhikya

Group A has shown 78.84% improvement in *Pipasadhikya* while in group B 67.27% relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant result was found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath*.

Excess loss of water decreases the water content (due to glycosuria) and increases the salt content in the body. This stimulates the thirst center in the hypothalamus, in turn, increases the intake  of water.  *Pipasadhikya* (polydipsia) is due to *Prabhta Mutrata*  . These symptoms are produced due *to Udakavaha Strotodushti* and vitiated *Pitta dosha*. In both Group drugs having *Kleda Shoshana*, thus reduces *the Kleda Nirmana* in the body. By reducing *Kleda* it reduced the quantity of urine which ultimately reduced the *pipasadhikya.*

## Karapadatala daha

Group A has shown 78.33% improvement in Karapadatala daha while in group B 59.32% relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant results were found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasadi Kwath.*

*Karapadatala daha* due to kleda (Insulin resistance) *Dosha, Dhatu kshya Leads* to *Shleshma hani, Dhatukshya, and pitta buddhi. Kara  Pada  Tala  Daha* is caused by to *ashayapkarshagati* of  *Pitta and due to the loss of Ambu content from the body. Salsaradi gana bhavit haritaki* helps in alleviating *Vata, Pitta,* and *Kapha Dosha. Strotoshodhana* and *Lekhana* properties help in removing the obstruction. *Kara Pada Tala Daha (*burning sensation in the palm and soles) symptoms are caused due to peripheral neuropathy caused by  Diabetes.

## Kara-Pada Suptata

Group A has shown 80.30 % improvement in *Karapadatala Suptata* while in group B 62.96% relief was found. In group A (p<0.0010) and group B (p<0.0010) statistically highly significant results were found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasadi Kwath.*

Diabetic neuropathy is a chronic condition & chronic hyperglycemia causes injury to the nerves throughout the body. Diabetic neuropathy is due to primarily metabolic and vascular factors. There is an increase in sorbitol & fructose, glycated end products, reactive oxygen species, and activation of protein kinase C in the diabetic state. All these factors lead to direct damage to the nerves. In *Madhumeha*, due to a chronic condition of disease, *Dhatukshaya* is manifested in the body *Kara Pada Tala Suptata is* caused due *to the ashayapkarshagati of*

*Kapha.* By the *vyanvayusanga*, *Kapha* gets dislocated to another place that may lead to the state of *Hasta Pada Suptata.* Though both groups showed highly significant results in *Kara-Padatala Daha* and *Kara-Pada Tala Suptata* Group showed better results than Group B percentage-wise.

Most of the drugs are *Trisdosha Shamaka and Strotoshodhaka.* Therefore, they act on vitiated Pitta and Vata which are responsible for *Kara-padatala Daha.* Due to *Rasayana* properties of *Salsaradi gana bhavit haritaki* pacifies the *Pitta & Vata* and reduces the *Karapadatala Suptata.*

### *Nindradhikya*

Group A showed 75.60% improvement in *Nindradhikya* while in group B 67.39% relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant result was found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath*.

### *Tandra*

Group A showed 78.83% improvement in *Tandra* while in group B 70.83 % relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant result was found but based on percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath*.

Though both groups showed highly significant results in *Nindradhikya* Group B showed better results than Group A percentage-wise. *Nindradhikya* and *Tandra* are due to *Kaphavruddhi* and in *Salsaaradi gana Bhavit haritaki* most of the drugs are having *Katu, Tikta & Kashaya rasa, Lekhana & Rukshana* property which acts as *Kaphashaman, Kledashoshana, Strotosodhana & Medoghna* and relieve the symptom of *Nindradhikya* and *Tandra.*

### *Swedadhikya*

Group A has shown 81.35% improvement in *Swedadhikya* while in group 67.69% relief was found. In group A (p<0.0010) and group B (p<0.0010) statistically highly significant results were found. Percentage-wise, *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath* in *Swedadhikya.*

In this present study, *Swedadhikya* was seen in most *Sthula* patients. As the *Sweda* is the *Mala* of the *Meda Dhatu*, in *Sthaulya,* increased *Meda dhatu* (due to *Dhatwagnimandhya*) causes *Swedadhikya.* Because of *Medasavruta vata* Overweight and obesity are among the main conditions related to hyperhidrosis which is due to decreased heat loss caused by the deposition of adipose tissue in the subcutaneous layer. Both drugs acted as *Medohara, Pachana*, *Lekhana*, *Strotosodhana,* and *Anulomana* Properties.

### *Angagandha*

Group A has shown 85.96% improvement in *Angagandha* while in group 66.66% relief was found. In group A (p<0001) and group B (p<0.0001 statistically insignificant result was found.

### *Daurbalya*

Group A has shown 81.35% improvement in *Daurbalya* while in group B 67.69% relief was found. In group A (p<0.0001) and group B (p<0.0001) statistically highly significant result was found but based on the percentage *Salsaradi gana bhavit haritaki* was found to be more effective than *Vijayasaradi kwath* in *Daurbalya.*

Increased excretion of glucose in the urine, water would also excrete along with the glucose in the urine due to osmosis, so there would be a decrease in the cellular uptake of glucose so cells use up fats and other nutrients which cause diabetic complications and *Dhatukshya* which may weakness in the diabetic patients. *Salsaradi gana bhavit haritaki* having *Kledashoshana, Srtotosodhana*, *Vata- -Kaphahara* properties helps to increase glucose uptake & due to *Rasayana* property of these drugs, proper *Dhatu poshana* is achieved.

## Effect on Objective criteria (FBS and PPBS)

The effect of therapy on fasting blood sugar is statistically highly significant ($p<0.0001$) in both Group A & B. Clinically Group A *Salsaradi gana bhavit haritaki* (30.25%) was more effective in reducing Fasting Blood sugar than Group B Vijayasradi with (21.24%) The effect of therapy on postprandial blood sugar is statistically extremely significant($p<0.0001$) in Both Group A & B. Clinically both group A(37.81%) & group B (31.47%) was more effective in reducing postprandial blood sugar.

There is a significant decrease in the mean score in the FBS parameter in both groups. However, after the completion of treatment, more significant results were found in group A *Salsaradi gana bhavit haritaki* in objective (FBS) criteria, when compared with group B Vijayasaradi. In the criteria of PPBS, statistically insignificant results are found in both groups, which suggests that the efficacy of both drugs is equal on the PPBS parameter.

**Observation: -**

In this study, a total of 50 patients were registered, and all patients had completed treatment along with follow-up. In the present study maximum i.e., 54% belonged to the age group of 41-50 years. 82% of patients were Hindus, 94% of patients were married 26% of the patients were educated up to higher secondary schooling. 42% were housewives and 32% were doing service 32% of patients belonged to the middle class and 64% of patients were from the upper-middle class. 90% of patients were from urban areas. 8% of patients had a positive family history. 2% of patients had continued medicine, and 20% of patients reported with gradual onset of the disease. 100% of the patients had chronicity in between Up to 1 year. 30% of Patients were found to have Vata-Kapha Prakriti, 92% of patients had Rajasika type Manas Prakriti, 54% of patients were of Madhyama Sara, and 13% were having Madhyama Samhanana. 48% of patients showed Madhyama Satva. 52% of patients showed Madhyama Abhyavaharana Shakti. 62% of patients showed Madhyama Jarana Shakti. 42% had Vishamagni which may be due to side effects of Anti-diabetic medicines or other reasons. 48% patients of showed the nature of Madhyama Koshtha. 70% of patients were vegetarian, Maximum of 96% and 88 % of patients were found to have Madhura and Lavana Rasa dominant diets respectively. 52% of patients had Vishamashana followed by 40% had Adhyashana in their Dietary Habits. 54% of patients showed sound sleep followed by 26% with excess sleep. Daytime sleeping leading Kapha dosha Vriddhi in the body. 38% of patients showed Avara Vyayama Shakti, which leads to Asthirikarana of Dhatus. Thus, the Dhatus formed results in Shaithilya. Higher incidence of various Nidanas like 78% patients with Guru Gunadhikyata, 96% patients with Madhura Rasadhikyata, also 88% had a history of lavanarasaadhika seven, 100% patient with Godhuma and 36% patients with Pishtanna seven, 48% with Mamsa Sevana, 68% with Diwaswapna,70% with Tyakta Vyayama, and 62% with Tyaktachintanama, 50 % Patient with Atyambupana,80% Patient with Avyayama etc were found to be etiological factors in Sthoola prameha. Reviewing of Symptoms: - In symptoms,

Prabhutamutrata was seen in 100% patients, Mutramadhuryata was seen in 62% patients, Avilmutrata was seen in 78% patients, Kshudhadhikya was seen in 88% patients, Pipasadhikya was seen in 84% patients, Karapadataladaha was seen in 82% patients, Karapadasuptata was seen in 80% patients, Swedadhikya was seen in 72% patients, Angagandha was seen in 66% patients, Nidradhikya was seen in 70% patients, Daurbalya was seen in 78% patients, Tandra was seen in 66% patients, Gala-Talu Shosha was seen in 82% patients.

**EFFECT OF THERAPY　RESULTS IN THE PATIENTS OF GROUP A:**

Patients were treated with Salsaradi gana bhavit haritaki in a dose of 2.5 to 7 gm Arohi avrohi kram two times a day Early morning on an empty stomach and in the evening with lukewarm water for 40 days and the effect of their treatment is being presented here.

In this group highly significant improvement seen in Prabhutamutrata(84.74%), Avilmutrata(80.%), Pipasadhikya(78.84%),Kshudhadhikya (73.46%).

Kara-Pada Taladaha (78.33%), Karapada Tala Suptata (80.30%), Swedadhikya (81.35%), Nindradhikya (75.60%), Mutramadhurya (75.91%), Daurbalya (74.54%), Tandra(78.94%) Gala-Talu Shosha (71.15%)significant result was found 85.96% in Angagandha. In this group, relief was observed in 30.25 % of F.B.S. and 37.81 % of P.P.B.S. which were statistically highly significant. In Group A: Marked improvement was found in 2 (8%) patients, Moderate improvement was found in 21 (84%) patients and Mild improvement was found in 2(8%%) patients.

**RESULTS IN THE PATIENTS OF GROUP B:**

25 Patients were treated with Vijayasaradi kwath in the dose of 20 ml two times a day Early morning on an empty stomach and in the evening with lukewarm water for 40 days and the effect of their treatment is being presented here. In this group, highly significant improvement seen in Prabhutamutrata(78.43%), Avilmutrata(69.76%), Kshudhadhikya (64%), Pipasadhikya (67.27%), Kara-Pada Tala Daha(78.33%), Kara-Pada-TalaSuptata(62.96%), Swedadhikya(67.39%), Nindradhikya(67.39%), Mutramadhurya(75.91%), Daurbalya (71.42%), Tandra(70.83%%) Gala-Talu Shosha(73.07%) significant result was found 66.67% in Angagandha.

In this group, relief was observed at 21.24% in F.B.S. and 40.85% in P.P.B.S. which were statistically highly significant. In Group B: Moderate improvement was found in 20(80%) patients, mild improvement was found in 4 (16%) patients, and 1(4%) patient remained unchanged.

**CONCLUSION**

Madhumeha is said to be Yapya Vyadhi & Anushangi in nature. Madhumeha is Santarpana Janya Vyadhi, Bahu Drava Sleshma, Meda and Kleda are the main Dushyas of the Prameha and play an important role in the etiopathogenesis of Madhumeha. Two types of patients of Madhumeha according to Bala of Rogi one is Sthoola (obese) and other is Krish (Asthenic). Apathya Nimittaj Prameha whose Signs and Symptoms can be correlated with Sthoola Premehi. A similar classification is seen in modern science as Obese (NIDDM) and Nonobese (IDDM) type or Type 1 and Type 2 DM. The sedentary lifestyle and physical inactivity increase the Kapha, Meda, and kleda in the body leading to the manifestation of madhumeha in sthoola and apathyanimittaja

Madhumeha or type 2 DM. Beejdushti in Sahaj Prameha (Congenital or type 1 DM) is a causative factor in the Samprapti of the disease. These factors cause insulin resistance and decrease insulin sensitivity in patients. Beta cell destruction or failure is an important factor in Sahaj Pramehi. The clinical study of 50 registered patients supports the classical theory of etiopathogenesis i.e. excessive consumption of Guru, Madhura, and Snigdha type of diet along with lack of exercise, day sleep, and chronic stress play a significant role in the causation of the disease. These factors increase Kapha, Meda, and Kleda in the body and also vitiate Vata by the theory of Avarana leading to clinical manifestations of the disease. Salsaradi gana bhavit haritaki (Group A) and Vijayasaradi kwath (Group B) both have shown significant results in subjective and objective parameters in enrolled patients. Although the overall improvement in both subjective and objective parameters was highly significant in both groups clinically percentage-wise improvement was more in Group A Salsaradi gana bhavit haritaki.

## REFERENCES

1. Sushruta Samhita sutra sthana 38/8-9
2. Charaka kalpa sthana 12/46-47.
3. Charaka Samhita, volume-1, Vidhyotini Vyakhaya, By Shree Satyanarayana Shastri, published by Chaukhamba Bharti Academy Nidana sthan 4/5, page no-632
4. Causes of Diabetes. National Institute of Diabetes and Digestive and Kidney Disease, June 2014.
5. Sushruta Samhita Acharya Sushruta "Ayurveda Tatva Sandipika" Hindi commentary, by Kaviraja Ambikadutta Shashtri, Published by Chaukhamba Sanskrit Prakashan, Nidana Sthana 27/6), page no - 330.
6. Sushruta Samhita Acharya Sushruta "Ayurveda Tatva Sandipika" Hindi commentary, by Kaviraja Ambikadutta Shashtri, Published by Chaukhamba Sanskrit Prakashan, Sutra Sthana 8-9