# "Comparativeevaluation of the efficacy of *Panchatikta Panchaprasutik Niruha Vasti* and lifestyle modification in Prediabetes (*Prameha Poorvaroopa*)"

## Poonam V. Ashtankar*[1], Punam Sawarkar[2], Manoj Patil[3], Kavita Singh[4]

*[1] PG Scholar, Dept of Panchakarma, Mahatma Gandhi Ayurved College Hospital & Research Centre, Salod; Datta Meghe Institute of Medical Sciences (DU), Wardha, Maharashtra, India. Email id- drashtankarpoonam@gmail.com

[2]Associate Professor, Dept of Panchakarma, Mahatma Gandhi Ayurved College Hospital & Research Centre, Salod; Datta Meghe Institute of Medical Sciences (DU), Wardha, Maharashtra, India.Email id- drsuple.punam@gmail.com

[3]Research Consultant, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Wardha.

[4]Professor, Computer Technology, Yeshwantrao Chavan College of Engineering, Nagpur

Original Article

Conflict of Interest: None

## Abstract

**Background:** Prediabetes is an intermediate state of hyperglycemia with glycaemic parameters above normal but below the diabetes threshold.In *Ayurveda*, it is correlated with *Prameha Poovaroopavastha*. The risk of developing diabetes remains high with an annual conversion rate 5-10%. Many other studies have shown that the efficacy of lifestyle intervention in diabetes prevention with a relative risk reduction of 40-70% in prediabetes adults. If we treat this disease in early stage then it checks the further pathogenesis of disease.

**Aim and objectives:** The aim of this study was to study the efficacy & safety of*Panchatikta Panchaprasutik Niruha Vasti* in Prediabetes.

**Material &Methods:** 30 patients of Prediabetes were recruited from OPD Pachakarma. In group A*Panchatikta Panchaprasutik Niruha Vasti*wasadministered for consecutive 15 days and lifestyle modification (diet, exercise and *Yoga* ) was advised  for the  group B.

**Results**: Highly significant (P=0.0001) result was found in the assessment of Subjective and objective parameters.

**Conclusion**: *Panchatikta Panchaprasutik Niruha Vasti* is highly effective to reduce blood and urine sugar level (fasting & postprandial).Moreover, it has significant effect to reduce weight as well as encouraging improvement  in symptoms of prediabetesas comparative to the  group B.
**Keywords**:Prediabetes,*Panchatikta Panchaprasutik Niruha Vasti,*Lifestyle modification,*Prameha Poorvaroopa*

## INTRODUCTION

Prediabetes is an intermediate state of hyperglycemia with glycogenic parameters above the normal but below the threshold for diabetes[1].It is a reversible condition, according to the National Institutes of Health (NIH). Though pre-diabetes diagnosis guidelines are not standardized across various international professional organizations, there remains a high risk of developing diabetes with an annual conversion rate of 5% - 10%[1]. Experimental evidence indicates a combination of prediabetes and complication of diabetes, such as early nephropathy, small fiber neuropathy, early retinopathy and risk of macro vascular disease. Although there is growing evidence to demonstrate the effectiveness of pharmacotherapy for avoiding the promotion of diabetes in individuals with Prediabetes , a number of  treatment options are associated with adverse reactions that restrict their use in Prediabetes. According to Centers for Disease Control and Prevention, 41 million U.S. adults aged between 40 and 74 have prediabetes[1]. Treatment may involve behavioral changes, such as diet control and exercise. Several studies have demonstrated the effectiveness of lifestyle changes in diabetes to reduce the risk significantly in 40-50 percent adults with prediabetes [2]. Type 2 diabetes can develop approximately 10 years if the prediabetes condition is not regulated by appropriate lifestyle changes. One research found that a 5- 10% weight loss achieved by lifestyle modifications substantially reduces the risk of diabetes[3].

Contemporary medication and various modalities available for the management of diabetes and Prediabetes have requirement of lifetime consumption evidences along with resultant multiple side effects. Therefore, there is, need to search an effective and safe treatment for the same.

In the *Ayurvedic* compendium, *Prameha* is defined as excessive urination (both in frequency and quantity) and turbidity of urine[4.] *Prameha* is *TridoshajKapha* predominant disease[5]. *AcharyaCharaka*, *Sushruta* and *Vagbhata* include it under *Ashtamahagada* (eight types of major diseases)*. Prameha* is in fact, a broad term that includes different types and stage the development of diabetes mellitus, pre-diabetic symptoms (*Prameha Poorvarupavastha*)plus complications. *Prameha Poorvarupavastha* explained in our ancient *Samhita* can be correlated with Prediabetes*.

As the treatment and preventive measures in *Poorvarupavastha* (fourth *Kriyakala*)[6] are very much appreciated. Therefore,if we treat this disease in *Poorvarupavastha*, it will check for further flourishing of disease pathogenesis.*Shodhana Karma* (*Purification* procedure) is the method for eliminating the vitiated *Doshas* from the body to eliminate the disease. The main treatment principle for *Prameha Chikitsa* is the elimination of *Kleda* (wetness). For *Kledaharana Shodhana Chikitsa* is  the best since *Prameha* is *Bahudosha Vasthajanya Vyadhi*[7.]*Vagbhata* has mentioned     about     5   types   of   *Shodhana (*Purgatative *)   which   are   known   as *Panchashodhana*(five penta bio purificatory procedure). *Niruha Vasti* (decoction enema) is one of them[8,9.].Among all *Panchkarma* procedures, *Vasti* therapy is the most  popular  due to its less  invasive   and  less  complicated  nature[9] andhaving  multidimensional  effect.  Among various*Vasti* preparations, *Panchatikta Panchaprasutik Niruha Vasti* is specially narrated for the management of *Prameha* [10]. Our ancient *Acharyas* emphasized  over dietic restrictions i.e.

lifestyle modifications   rather than *Shodhana Chikitsa*, for prevention and management of *Prameha.*So this study was designed to evaluate the comparative effect of *Panchatikta Panchaprasutik Niruha Vasti*and lifestyle modification in the management of Prediabetes.

**AIM AND OBJECTIVES**

<u>**Aim:**</u>

To study the comparative evaluation of *Panchatikta Panchaprasutik NiruhaVasti* and lifestyle modification in Prediabetes (*Prameha Poorvarupa*).

<u>**Objectives:**</u>

1. To assess the efficacy of *Panchatikta Panchaprasutik Niruha Vasti* in the management of symptoms of Prediabetes and Blood Sugar level.

2. To assess the efficacy of lifestyle modification in the management of symptoms of Prediabetes and Blood Sugar level.

3. To compare the effect of *Panchtikta Panchaprasutik Niruha Vasti* andlifestyle modification in the management of symptoms of Prediabetes and Blood Sugar level.

**MATERIAL AND METHOD**

**The locus of the study:**A total 30 patients  diagnosed with Prediabetes were registered for the study from the outpatient and inpatient of Department of Panchakarma, Mahatma Gandhi *Ayurved* Medical College , Hospital and Research Centre, Wardha, Maharashtra, India. The Informed consent was obtained from the all  patients before undergoing  the intervention.

**CTRI registration number :**CTRI/2020/01/022695

**IEC clearance reference number :** DMIMS (DU)/IEC/May-2017-18/7261

**Study Type:** Interventional

**Study Design:** RandomizedInterventional Open label comparative clinical trial (Double Arm study)

**Sample selection technique:** Simple randomization by lottery method

**Sample Size & Grouping:** Total 30 patients (15 patients in each group)

Group A (Trial)- 15 patients (*Panchatikta Panchaprasutik Niruha Vasti*)

Group B( Control)- 15 patients (Lifestyle modification)

**Inclusion Criteria:**

Newly diagnosed patients of Prediabetes i.e. Fasting Blood Sugar level (100-125mg/dl) and Post Prandial Blood Sugar level (140-199 mg/dl) of either sex between the age group of 30 – 60 years were included for the study.

**Exclusion Criteria:**

Following patients were excluded from the study.

1. Gestational diabetes
2. Pregnant and lactating mothers
3. Patients with any major systemic medical or surgical illness
4. Patients having fissure in ano, piles
5. Patients having *Mandagni / Samavastha* symptoms

**Data Collection:**

Examination of patient was done thoroughly with the help of subjective and objective parameters. Detail history pertaining to the mode of onset, previous history, family history, habits, *Ashtavidha Pariksha* and systemic examination findings were noted. Investigations were done [Blood Sugar (Fasting and postprandial) and Urine Sugar] before & after intervention for assessment.

**Investigations for screening –**

All patients were screened through history and routine investigations.

a) **Routine Investigations:** Hemoglobin percentage, Erythrocyte sedimentation rate, Fasting and post prandial blood Sugar, Urine sugar, Lipid profile, Electro Cardio Graph were carried of each patient before recruitment to exclude other clinical conditions.
b) **Specific Investigations:** Blood Sugar (fasting and post prandial) and Urine Sugar (on 0 day, 15th day and 45th day).

**Table 1: Diagnostic criteria[11]**

| Diabetes test | Normal | Prediabetes | Diabetes |
|---|---|---|---|
| Fasting blood sugar, mg/dL | < 100 | 100-125 | > 125 |
| Post prandial blood sugar mg/dL | < 140 | 140-199 | > 199 |

**Treatment :**

a) **Group A**

**Table 2: Composition of *Panchatikta Panchaprasutik Sasneha Niruha Vasti*[10]**

| Composition of *VastiDravya* | Time of administration | Duration | Specific precaution |
|---|---|---|---|
| *Qwath* prepared from (powder of *Patol, Nimba, Bhunimba, Rasana, Saptaparna, Sarshapa (Kalka)* - 540 ml<br>+ *Saindhva* – 10gm<br>+Honey  - 15ml<br>+*Go ghrita  - 80* ml<br>+ *Sarshpa Kalka* – *30* gm | -At morning with empty stomach (up to10:30 am) | -Once daily (For 15 days) | -Advice patient to come with empty stomach, previously food well digested. |

b) **Group B**

**Table 3:Lifestyle modification**:

| Lifestyle modification (daily for 45 days) | |
|---|---|
| Diet [12] | Cereals – *Yava* (Barley), *Godhuma* (wheat), *Puran Shali* (old rice) |
| | Pulses – *Mudga*(Green gram) |
| | Condiments – *Haridra* (turmeric), *Marich* (pepper), *Lasuna*(garlic),*Shunthi* (dry ginger), *Methika* (fenugreek)**.** |
| Exercise | -Morning walk 30 minutes  daily at morning |
| *Yoga*[13] | *Kapalbhati*<br>*Suryanamskar* |

**Study Duration:**

In Group A, initially 15 day of intervention and follow up period after 45$^{h}$ days. In Group B, 45 day of intervention and follow up period after 45$^{th}$ days.The total study duration is 45 days.

**Procedure of*Vasti*:**

- *Poorvakarma* **(Pre procedural preparation)**

**a)Preparation of *Vasti*:-**

**i] Preparation of *Kwath***

To boil one part of drug in16 parts of water in the low flame and reducing it to1/8$^{th}$ of the original volume. It also directs not to cover the vessel with lid, as the decoction becomes *Guru* and heavy for digestion[14].

**ii]Preparation of *Vasti Dravya***

*Saindhava* (10gm), Honey (15ml) will be mixed and stirred in a clean vessel with a pestle after that, *Go Ghrita* (1 *Prasuta*-80 grams) will be added and stirred. Paste of *Sarshapa* which was prepared by the method of *Kalka Kalpana*[16](30 grams) will be added and mixed thoroughly. Then prepared *Kalka* will be added to decoction, which will be prepared by *Kwatha Kalpana*[17] to make homogenous emulsion and then will be heated it gently by water bath.This mixture is poured in to enema pot and it will be fixed with simple rubber catheter No.09[15].

**b)Preparation of patient:**

- A patient will be advised to come at 10.30 a.m. with light breakfast at 7 a.m**.**

- local massage over buttocks, hip, both thigh and lumber region with *Tila Taila* (50ml) will be performed for 10 minutes followed by *Dashmoola Kwath Nadi Swedana* for 10 minutes.

- Patient will be made to lay down in left lateral position

- *Pradhana Karma* **(Main procedure)**

Anus will be adequately lubricated with little quantity of oil is applied on patient's anus and nozzle of *Vasti Yantra.* Before administration of *Vasti Dravya*, 5 -10 ml *Vasti Dravya* will be allowed to spill out from catheter to avoid air entry into the anal canal.
The nozzle will be gently inserted up to 1.5-2 cm in anal region parallel to vertebral column and enema cancontaining *Vasti Dravya* will be held at some height of the patient and *Vasti Dravya* will be allowed to enter into the large intestine of the patient, through anal canal. Due to gravitational force until only small quantity of *Vasti Dravya* will remain in the Enema pot to avoid air insertion.Then nozzle will be removed gently and patient will be allowed to lie down on supine position until he/she feels urge to excrete.

- ***Pashchat Karma* (Post procedural precaution)**

After evacuation of the bowel, the patient may take hot water bath and semisolid diet[18].

**Diet and Restrictions:**

All recruited Patients were advised to take light diet free from *Madhur, Sneha,* and *KatuRasa* and advised not to indulge in *Ashtamahadoshka Vajra Vishayas* **(***Uchhabhashya, Rathakshobha, Atichakramana, Atiaasana, Ajirna, Ahitabhiojana, Diwaswapna* and *Maithuna*).

**Method of Assessment of clinical response:**

Assessment was done based on subjective (*Prameha Poorvarupa*[19]) and objective parameters [Blood Sugar level (fasting and post prandial)], Urine Sugar and Weight before a day of treatment, just after the day of treatment and Follow up visit (0 day, 15th day and 45th daythat are discussed in result section.

a) **Subjective variables**
   1. *Atiswedapravritti* (Excessive sweating)

   2. *Shithilangata* (Flabbiness of body*Galatalushosha* (Dryness of the throat and palate)

   3. *Ghanangata* (Bulkiness of the body)

   4. *Karapadadaha* (Burning sensation in hands and legs)

   5. *Prabhutmutrata* (Excessive urination)
b) **Objective Criteria**
   1. Fasting blood sugar (FBS)
   2. Post prandial blood sugar (PPBS)
   3. Urine sugar
   4. Weight

**Assessment**

**Table 4 : Criteria for Assessment** of *Prameha Poorvaroopa*&Urine sugar was done on the basis of its presence or Absence)

| Sr. No. | Subjective Criteria | Present | Absent |
|---------|---------------------|---------|--------|
| 1. | *Atiswedapravritti* | 1 | 0 |
| 2. | *Shithilangata* | 1 | 0 |
| 3. | *GalataluShosha* | 1 | 0 |

| 4. | *Ghanangata* | 1 | 0 |
| 5. | *Karapadadaha* | 1 | 0 |
| Sr. No. | Objective Criteria | Present | Absent |
| 1. | Urine Sugar | 1 | 0 |

**Observation and result:**

**Subjective criteria:**

Table 5 : Assessment based on relief in subjective criteria

| | Range | Group A | Group B | Total |
|---|---|---|---|---|
| Complete Remission | 100% | 13(86.67%) | 2(13.33%) | 15(50%) |
| Marked Improvement | 75-99% | 0(0%) | 0(0%) | 0(0%) |
| Moderate Improvement | 50-74% | 2(13.33%) | 5(33.33%) | 7(23.33%) |
| Mild Improvement | 25-49% | 0(0%) | 4(26.67%) | 4(13.33%) |
| Unchanged | <25% | 0(0%) | 4(26.67%) | 4(13.33%) |

From above table & graph, it is reflected that in group A, there was marked, only 13 .33 % patients had moderate relief and there was not a single patient in this group who did not have any relief. However, there was observed moderate & mild relief of subjective parameters in 33.33% & 26.67% patients of group B respectively. 26.67% patients of this group had no relief in symptoms.

Maximum i.e. 86.67% patients had got complete relief in symptoms of Prediabetes due to intervention of *Vasti,* which is more than those effect induced by Group B i.e. 13.33%. It can be concluded that Group A is more effective to induce relief in subjective parameters than group B.

**Objective Criteria:**

Table 6: Comparison of Fasting Blood Sugar in two groups

| FBS | Before t/t | After t/t | Follow Up Visit |
|---|---|---|---|
| **Group A** | 122.06±3.76 | 81.66±11.44 | 86.33±12.02 |

| t-value | - | 14.30 | 11.022 |
|---|---|---|---|
| p-value | - | 0.0001,S | 0.0001,S |
| **Group B** | 121.66±3.75 | 118.26±4.72 | 114.93±5.21 |
| t-value | - | 6.27 | 11.27 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Comparison between Group A and Group B** | | | |
| t-value | 0.29 | 11.44 | 8.45 |
| p-value | 0.77,NS | 0.0001,S | 0.0001,S |

In group A, Fasting Blood Glucose level significantly reduced from mean value of 122.0 to 81.66 for t value 14.30 and P value 0.0001, and it remain reduced in follow up visit also. It shows that, *Panchatikta Panchaprasutik Niruha Vasti* is significantly effective to reduce Fasting Blood Sugar level and its effect is going on even after 45th day also, for P value 0.0001and t value 11.022.

In group B though there was significant reduction in Fasting Blood Sugar level from  mean value of 121.66 to 118.26  after intervention,  with t value 6.27 and P value 0.0001. There was P value 0.0001. However, this reduction was not within normal range.

While comparison of group A and B before intervention, non significant P value 0.77 shows that there is uniform distribution in group A and B. While comparison between two group with significant reduction in Fasting Blood Glucose level with t value 11.44 & 8.45 just after intervention & in follow up visit respectively for P value 0.0001, it  is reflected that *Vasti* group is more effective than group B to reduce  Fasting Blood Glucose level.

Table 7: Comparison of Post Prandial Blood Sugar in two groups

| PPBS | Before t/t | After t/t | Follow Up Visit |
|---|---|---|---|
| **Group A** | 187.26±12.57 | 128.48±8.53 | 132.46±6.25 |
| t-value | - | 14.30 | 11.022 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Group B** | 157.73±10.57 | 155.06±10.16 | 149.86±10.86 |
| t-value | - | 8.47 | 8.40 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Comparison between Group A and Group B** | | | |
| t-value | 6.72 | 7.76 | 5.37 |

| p-value | 0.0001,S | 0.0001,S | 0.0001,S |
|---|---|---|---|

In group A, Post Prandial Blood Glucose level significantly reduced from mean value of 187.26 to 128.48 with t value 14.30 for P value 0.0001. And it remain reduced in follow up visit also with t value 11.022 for P value 0.0001 which is reflected that, *Panchatikta Panchaprasutik Niruha Vasti* is significantly effective to reduce Post Prandial Blood Sugar level just after intervention & even on 45th day also.

In group B, there was significant reduction in Post Prandial Blood Glucose level from mean value of 157.73 to 155.06 after intervention, with t value 8.47 for P value 0.0001. There was again further significant reduction in Post Prandial Blood Sugar level at follow up with t value 8.40 for P value 0.0001, But reduction in both visits was not within normal range.

While comparison of group A and B before treatment, significant P value 0.0001 shows that there is not uniform distribution in group A and B. While comparison between two groups after treatment, significant t value 7.76 & 5.37 for P value 0.0001 at just after intervention and at follow up visit respectively shows that, *Vasti* group is more effective to reduce Post Prandial Blood Glucose level than group B.

Table 8: Distribution of patients in two groups according to Urine Sugar

| Urine Sugar | Before t/t | After t/t | Follow Up Visit |
|---|---|---|---|
| **Group A** | | | |
| Absent | 2(13.3%) | 15(100%) | 15(100%) |
| Present | 13(86.7%) | 0(0%) | 0(0%) |
| χ2-value | - | 22.94 | 22.94 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Group B** | | | |
| Absent | 7(46.7%) | 8(53.3%) | 11(73.3%) |
| Present | 8(53.3%) | 7(46.7%) | 4(26.7%) |
| χ2-value | - | 0.13 | 2.22 |
| p-value | - | 0.71,NS | 0.13,NS |
| **Comparison between Group A and Group B** | | | |
| χ2-value | 3.96 | 9.13 | 4.61 |

| p-value | 0.046,S | 0.002,S | 0.031,S |

In group A, there were 13 patients who had positive Urine Sugar test among total 15 patients recruited in this group & rest of 2 patients had negative Urine Sugar. All 13 patients had got Urine Glucose level significantly reduced just after intervention of *Vasti*& this result remained persistent even at follow up visit also. This significant decrease in Urine Sugar was with t value 22.4 for p value 0.0001 for both visits, which shows that, *Panchatikta Panchaprasutik Niruha Vasti* is significantly effective to reduce Urine Sugar level.

 In group B, there were 8 patients who had positive Urine Sugar test among total 15 patients recruited in this group & rest of 7 patients had negative Urine Sugar. Only one patient had got Urine Glucose level significantly reduced just after lifestyle modification. This reduction in Urine Glucose level was insignificant with Chi-square value 0.13 for P value 0.71 & Chi-square value 2.22 for P value 0.13 just after intervention & at follow up visit respectively.

While comparison of group A and B before intervention, significant P value 0.046 shows that there is not uniform distribution in group A and B. While comparison between two groups, with significant reduction in Urine Glucose level after intervention with Chi-square value 9.13 for P value 0.002, and Chi-square value 4.61 for P value 0.031 at follow up visit. Which reflects that *Vasti* group is more effective to reduce Urine Glucose level just after intervention & at follow up visit than group B.

Table 9: Comparison of Weight in two groups

| Weight | Before t/t | After t/t | Follow Up Visit |
|---|---|---|---|
| **Group A** | 72.80±8.25 | 69.66±8.44 | 70.20±8.37 |
| t-value | - | 18.96 | 15.92 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Group B** | 69.33±6.36 | 68.06±6.12 | 66.93±6.37 |
| t-value | - | 10.71 | 18.33 |
| p-value | - | 0.0001,S | 0.0001,S |
| **Comparison between Group A and Group B** | | | |
| t-value | 1.28 | 0.59 | 1.20 |
| p-value | 0.20,NS | 0.55,NS | 0.23,NS |

In group A, mean Weight of patients significantly reduced from mean value 72.80±8.25 to 69.66±8.44 after intervention with t value 18.96 for P value 0.0001, and it remain reduced in follow up visit also. It shows that *Panchatikta Panchaprasutik Niruha Vasti* is significantly effective to reduce Weight and its effect is going on up to follow up visit i.e. after 45th day, with t value 15.92 for P value 0.0001.

In group B, there was significant reduction in Weight from mean value 69.33±6.36 to 68.06±6.12 just after intervention with t value 10.71 for P value 0.0001 .There was again further significant reduction in Weight up to follow up with t value 18.33 for P value 0.0001. While comparison of group A and B before treatment, non significant P value 0.20 shows that there is uniform distribution in group A and B. While comparison between two group there was non significant reduction in Weight just after intervention & at follow up visit, which shows that *Panchatikta Panchaprasutik Niruha Vasti* and lifestyle modification has same effect to reduce Weight persistently after follow up visit also.


**Discussion:**

Considering all factors involved in the pathogenesis of *PramehaPoorvaroopa*, the main treatment principle is to remove *Kleda* in this case and *VastiKarma* was already told by *AcharyaCharaka* as it corrects the vitiation of *Vata* to stabilize its normal functions and also counteracting the vitiated *Kapha*, *Kleda*, and *Meda* by using specific drugs. So specially prepared medicated enema was prescribed in this case followed by lifestyle modification. After intervention, patient got significant relief clinically as well as improvement were observed in blood and urine sugar level. Given treatment protocol mainly comprises of *Kledaharana*, which helps the breakdown of pathogenesis of prediabetes in this patient.Probable mode of action of all interventions are given below:

**Comparative discussion on subjcetive criteria along with mode of action of *Vasti*:**

There was highly significant result occurred in*Atiswedapravritti* due to *Panchatikta Panchaprasutik Niruha Vasti* in group A. In contrast, no significant reduction found in *Atiswedapravritti* in the control group. It can be justified as,*Atiswedapravritti* occurs due to *Meda Dhatu Dushti*. In addition, *Aampachana*, *Kleda Upshoshana*, *Strotoshodhana* and *Medohar* properties[20] present in various drugs used in *Panchatikta Panchaprasutik Niruha Vasti* reduced the vitiation of *Meda,* and ultimately it resulted into relief in the symptom, whichispersistent after follow up visit also.*PanchatiktaPanchaprasutikNiruhaVasti* may reached at deeper tissue e.g. *Meda*.Again there was highly significant result occurred in *Shithilangata* due to *Panchatikta Panchaprasutik Niruha Vasti* in group A. In contrast, no significant reduction found in *Shithilangata* in the control group. It can be justified as, the symptoms of *Shithilangata* is generally developed due to predominance of *Guru Guna* and vitiation of *Kapha* as well as *Kleda*. The administration of this *Vasti* induces *Laghuta* in the body due to its *Rasayana* and immunomodulator effect, which ultimately resulted in to reduction in *Shithilangata*[21].

Significant result occurred in *Galatalushosha* due to *Panchatikta Panchaprasutik Niruha Vasti* in group A . In contrast, no significant reduction found in *Galatalushosha* in the control group. *Galatalushosha*occurs due to vitiation of *Rasadhatu,Pitta Prakopa* and due to vitiation of

*Udakvaha Strotodushti.Murdha*, *Talu* and *Kloma* are the *Mulsthana* of *Udakvaha Strotas.* In Prediabetes there is occurrence of *Galatalushosha* due to *KhaVaigunnya* of *Kloma* ie, pancreas. The inefficiency of pancreatic cell especially insulin receptors is the basic pathology of prediabetes[22]. In the contemporary science, the development of *Galatalushosha* may occur because of extra evacuation of water through body through polyuria in such patients.Above said effect of the intervention may occurred as various drugs e.g. *Patol*, *Nimba*, *Bhunimba*, *Rasna*, *Saptaparna* in *PanchatiktaPanchaprasutikNiruhaVasti* directly acts on the insulin receptor on beta cells which increases the sensitivity of these cells. It may occur due to *Pittashamak* property of *Goghrita* used in this *Vasti*[23].Again there was significant result occurred in *Ghanangata* after intervention of *Panchatikta Panchaprasutik Niruha Vasti* in-group A. However, there was no significant reduction found incontrol group after giving lifestyle modification. *Ghanangata* occurs due to *Kapha Prakopa*, which leads to vitiation of *Kleda* and *Meda* and all ingredients present in the *Vasti* have specific actions e.g. *Kaphaghna*, *Medohara* and *Kledahara* [20], which drains *Abhishyanda* and leads to purification of micro as well as macro pores of multiple channels, due to expulsion of *Kleda*[24].

Significant effect in reliefof *Karapadadaha* due to trial *Vasti.*It wasdeveloped due to vitiation of *Pitta,* due to elimination of excess water from the body (*Bahumutrata*)[25]. In addition, most of the drugs used in the *Vasti* are *Pittashamak* in nature[20] and ultimately reduces *Karapadadaha.* Accordingto modern science*, Karapadadaha* comes under the category of neuropathic symptom, which is developed as a result of neuronal damage (*Majja Dhatu*). The deep penetration capacity of these *Vasti* induces repairing of neural end, which ultimately decreases the symptoms of *Karapadadaha.* This result can be again enhanced by neuroprotective effect of cow ghee[26] used in the *Vasti* as it repairs the myelin sheath over the neuron.

In the symptom of *Prabhutmutrata* there washighly significant reduction occur due to *Panchatikta Panchaprasutik Niruha Vasti* in-group A. Moreover, there was significant reduction found in symptoms of *Prabhutmutrata* in control group. The basic pathology involved in prediabetes is vitiation of *Kapha* or formation of *Kleda* in excess and the elimination of *Kleda* out of body is the chief function of *Mutra*[27].Therefore, frequency of micturation also increases in order to remove excess *Kleda* from the body. The drugs, which are present in the *Vasti*, has *Kledahara* property by virtue of its *Tikta* and *RukshaGuna*[20]. All the drugs absorb *Kleda* and *KaphaGuna* andultimately reduction in polyuria.

**Comparative discussion on objective criteria along with mode of action:**

There is significant reduction occur in FBS and PPBS after intervention of *Panchatikta Panchaprasutik Niruha Vasti*. In group A, these significant results were persistent even at follow up visit also.Though, there is significant reduction found in FBS and PPBS in control group after lifestyle modification, these reduction were  not within normal range which shows that,  *Vasti* group is more effective than group B to reduce FBS and PPBS. This greater efficacy of *Vasti* group can be justified based on previous studies conducted on *Panchatikta* drugs, which shows an impact on pancreatic beta cells through insulin release or secretion in addition to enhancing

peripheral insulin sensitivity. Therefore, it efficiently induces a substantial decrease in blood sugar levels due to the ingredients in the trial group[28].

There was significant reduction occur in Urine Sugar level after the intervention of *Panchatikta Panchaprasutik Niruha Vasti* and similar result was persistent even at follow up visit. While insignificant results were found in the control group showing greater efficacy of *Vasti*.It can be justified based on conclusions of various studies showing that, different drugs in this *Vasti* might have an impact on pancreatic beta cells through insulin release or secretion in addition to enhancing peripheral insulin sensitivity. It induces a substantial decrease in blood sugar levels then reduction occurs automatically in Urine Sugar level.

It is reflected that, *Panchatikta Panchaprasutik Niruha Vasti* is more effective to reduce weight than lifestyle modifications. There was significant reduction occur in Weight in both groups after interventions & it is reflected that, *Panchatikta Panchaprasutik Niruha Vasti* is more effective to reduce weight than lifestyle modifications.  Weight gain observed in *PramehaPoorvarupavastha* may be due to *Medo Dushti.* The greater effect of *Vasti* in weight reduction  may occurred as all ingredients present in the *Vasti* have *Medohara* and *Lekhana* action, by its *Katu ,Tikta, Kashaya Rasa* and *Ushna Veerya*[20], which drains *Abhishyanda* and leads to purification of micro as well macro pores of multiple channels, due to expulsion of *Kleda.* Itleads to proper secretion and circulation in *Annavaha- Strotas* and peripheral organs, which leads to reduction in Weight[29.]

**Mode of action of action of lifestyle modifications:**
Reducing high calorie consumption improves insulin sensitivity and lowers blood sugar level as well as, eating heart healthy diet, losing excess weight. Physical activity like, brisk walking, is essential for losing weight, as it allows to burn calories[30]. After 30 minutes of brisk walking every day, it helps to burn 150 more calories a day. *Yoga* such as *Kapalbhati* and *Suryanamaskar* that are very effective breathing exercise, to stimulate and improve the functions of the pancreas naturally. To generate sufficient insulin hormone, and to improve the metabolism as well as immune system. It helps to burn belly fat that ultimately resulted into lose weight, which helps to reduce the risk of diabetes[31].

A number of studies on diabetes and prediabetes in modern medicine were reviewed[32,33,34]. Rathi et al conducted nerve conduction studies of peripheral motor and sensory nerves in the subjects with prediabetes[35]. Ray et al studied the effects of Alirocumab on cardiovascular and metabolic outcomes after acute coronary syndrome in patients with diabetes[36]. Shrivastava et al conducted assessment of Mean Platelet Volume (MPV) in subjects with type 2 diabetes mellitus[37].

**Conclusion:**

In the current study, the intervention in-group A i.e. *Panchtikta Panchaprasutik Vasti* was foundsignificantly effective to reduce all symptoms of prediabetes (*Prameha Poorvarupa*) Moreover, this intervention was also found highly effective to reduce Blood Sugar fasting and post prandial after intervention with complete absence of urine sugar Level with sustainable result even in follow up visit also. It is very interesting to note that this *Vasti* is also effective to

reduce weight by 4.31% in the trial group.On comparison between two groups, group A  i.e. *Panchatikta Panchaprasutik Niruha Vasti* is more effective than group B..Further research multi centric studies with  large  sample size should be undertaken to embark this conclusion.

**References:**

1. Bansal N, Prediabetes diagnosis and treatment: A review. World J Diabetes 2015; 6(2): 296-303 Available from: URL: http://www. wjgnet.com/1948-9358/full/v6/i2/296.htm DOI: http://dx.doi. org/10.4239/wjd.v6.i2.296.

2. Atlanta G. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, Department of Health and Human Services 2014;

3. American Diabetes Association and National Institute of Diabetess, Digestive and Kidney Diseases. The prevention or delay of type 2 diabetes. Diabetes Care 2002; 25: P.742-749.

4. Tripathi B, editor. Pramehanidana Adhyaya. Chapter 10, Verse 7. In: Vagbhata, Ashatang Hrudaya.  Nidansthana. Delhi, India: Chaukhamaba Sanskrit Pratishthan; 2015. p. 495.

5. Shukla V, Tripathi R, editor. Prameha Nidana Adhyaya. Chapter 4, Verse 5-8. In: Agnivesh,Charak Samhita, Nidansthana. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p. 502-503.

6. Sharma A, editor. Vranaprasnadhyaya. Chapter 21,Verse 33.In: Sushrut, Sushruta Samhita, Sutrasthana.Varanasi, India Chaukhamba Surbharati Prakashana,2015.p.187-188.

7. Shukla V, Tripathi R, editor. Chikitsasthana; Prameha chikitsa Adhyaya.Verse 51. In: Agnivesh , Charak Samhita. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p. 176.

8. Tripathi B, editor. Chikitsasthana;PramehachikitsaAdhyaya.Vagbhata, AshatangHrudaya. Chapter 13, Verse 2-3. Delhi, India: Chaukhamaba Sanskrit Pratishthan; 2015. p. 715.

9. Parwe Shweta D. Effect of Gomutra Niruha Basti on Sthaulya (obesity).

10. Patil V. Principles and Practice of Panchakarma. A Comprehensive Book for U.G ., P.G., Researchers and Practitioners. Delhi, India : Published by  Chaukhmba Publication; 2018. P .417.

11. Shukla V, Tripathi R, editor. Sidhistana; Prasruyogiya siddhi Adhyaya.Verse 8. In: Agnivesh ,CharakSamhita. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p.938.

12. Rao S, editor. Siddhi*Vasti*kalpa Adhyaya.Chapter 5, Verse 2. In: Vagbhata, Astanga Sangraha, Kalpa Sthana. 1st edition. Varanasi, India: Choukhamba Krishnadas Academy; 2008. p.625.

13. Shukla V, Tripathi R, editor. Prameha chikitsa Adhyaya. Chapter 6, Verse 19, 20,21. In: Agnivesh, Charak Samhita, chikitsasthana. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p.171.

14. Ministry of ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy(Ayush) Govt. of India. Protocol for Prevention and control of Diabetes through Ayurveda; Printed at : J.K. Offset Graphics Pvt. Ltd., Okhla, Phase-I, New Delhi-110020:2016.

15. Murthy SK, editor. Qwath Kalpana. Chapter 2, Verse1-3 . In: Sharangadhara, Sharangadhar Samhita, Varanasi, India: Chaukhamba Orientalia; 2012. p. 56.

16. Shukla V, Tripathi R, editor. *Vasti*sutriya siddhi Adhyaya. Chapter 3, Verse 23. In: Agnivesh, Charak Samhita, Siddhi Shtana. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p.

17. Murthy S, editor. Kalka Kalpana. Chapter 5, Verse 1-2. In: Sharangadhara, Sharangadhar Samhita, Varanasi, India: Chaukhamba Orientalia; 2012. p.81.

18. Murthy SK, editor. Qwath Kalpana. Chapter 2, Verse1-3 . In: Sharangadhara, Sharangadhar Samhita, Varanasi, India: Chaukhamba Orientalia; 2012. p. 56.

19. Shukla V, Tripathi R, editor. *Vasti*sutriya siddhi Adhyaya. Chaper 3, Verse 26. In: Agnivesh, Charak Samhita, Siddhi Shtana. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2011. p. 902.

20. Shukla V, editor. Prameha Chikitsa Adhyaya. Chapter 6, Verse 13-14.In: Charak Samhita of Agnivesh, Chikitsasthana. Delhi, India: Chaukhamba Sanskrit Pratisthana; 2010. p.170.

21. Deshpande AP, Subhash R, editors. Textbook of DravaygunaVigyan (English), Part-2, A.R. Nandurkar. Shaniwar Peth, India:Proficient Publishing House; 2007.

22. Ratnakar V. Efficacy of Yoga*Vasti* Comprising of Panchatikta Niruha *Vasti*& Madanaditaila Anuvasana*Vasti* in the Management of Kitibha Kushta Vis-À-Vis Psoriasis. Rasamruta, 4:4, June 2012.

23. Sinha K, Sahu L, Lohith B. Critical review on Role of Shodhana in Prameha With Special refferance to Diabetes Mellitus. Sinha Kaushal et al / Int. J. Res. Ayurveda Pharm. 8 (5), 2017.

24. https://www.vedicgiftshop.com/cow-products/panchagavya-uses-benefits-preparation/

25. Ganpat M, Joshi Y, Asutkar V. Study of role of Panchatikta *Vasti*in Abhishyanda Pradhana. Volume 16, Issue 4 Ver. VI (April. 2017), PP 64-68.

26. Gusain M, Chaudhari K, Srivastav A, Shukla G. A review on the role of Vastikarma in Daibetes Mellitus. European Journal of Pharmaceutical and Medi cal Research *ejpmr, 2017,4(11), 178-182.*

27. Khiratkar A, Satpute S. "Prediabetic Diagnosis through Prameha *Poorvarupa*" IRJIMS, Jul-Sep 2018, Volume:1(Issue:1):81-86

28. Karandikar Y, Bansude A, Angadi E. Comparison between the effect of Cow Ghee and Butter on Memory and Lipid Profile of Wistar Rats.Journal of Clinical and Diagnostic research.2016 Sep, Vol-10(9):FF11-FF15.

29. Burse R, Dhimdhime R, Jumnake V. Study of Mutra and Mutravaha Strotas in Madhumeha-Research Article. Ejpmr, 2019,6(12),487-493.

30. Parwe SD, Nisargandha MA. EFFECT OF PANCHALAVAN CHURNA WITH GOGHRUTA IN MALAVSTAMBHA (CONSTIPATION).

31. Nugroho A. Purnomo K, Sunarwidh A. Blood Glucose Reduction by Combination of Andrographis paniculata (Burm. f.) Ness Herbs and Azadirachta indica A. Juss Leaves in Alloxan-Induced Diabetic Rats. Journal of Applied Pharmaceutical Science 4 (09); 2014: 030-035.

32. Gaidhane, Shilpa, Nazli Khatib, Quazi Syed Zahiruddin, Abhay Gaidhane, Sailesh Kukade, and Sanjay Zodpey. "Perceptions of Primary Care Doctors towards Type 2 Diabetes Mellitus and Challenges for Care at Primary Care Level in India." *INTERNATIONAL*

*JOURNAL OF DIABETES IN DEVELOPING COUNTRIES* 35, no. 1 (March 2015): 14–18. https://doi.org/10.1007/s13410-014-0199-6.

33. Gondivkar, Shailesh M., Atul Indurkar, Shirish Degwekar, and Rahul Bhowate. "Evaluation of Gustatory Function in Patients with Diabetes Mellitus Type 2." *ORAL SURGERY ORAL MEDICINE ORAL PATHOLOGY ORAL RADIOLOGY AND ENDODONTOLOGY* 108, no. 6 (December 2009): 876–80. https://doi.org/10.1016/j.tripleo.2009.08.015.

34. Khatib, N., S. Gaidhane, A. Gaidhane, and Z. Quazi. "M-HEALTH INTERVENTION FOR TYPE II DIABETES MELLITUS PATIENTS IN INDIAN RURAL AREAS." *DIABETES TECHNOLOGY & THERAPEUTICS* 16, no. 1 (February 1, 2014): A95–96.

35. Rathi, Nikhil, Bharati Taksande, and Sunil Kumar. "Nerve Conduction Studies of Peripheral Motor and Sensory Nerves in the Subjects With Prediabetes." *JOURNAL OF ENDOCRINOLOGY AND METABOLISM* 9, no. 5 (October 2019): 147–50. https://doi.org/10.14740/jem602.

36. Ray, Kausik K., Helen M. Colhoun, Michael Szarek, Marie Baccara-Dinet, Deepak L. Bhatt, Vera A. Bittner, Andrzej J. Budaj, et al. "Effects of Alirocumab on Cardiovascular and Metabolic Outcomes after Acute Coronary Syndrome in Patients with or without Diabetes: A Prespecified Analysis of the ODYSSEY OUTCOMES Randomised Controlled Trial." *LANCET DIABETES & ENDOCRINOLOGY* 7, no. 8 (August 2019): 618–28. https://doi.org/10.1016/S2213-8587(19)30158-5.

37. Shrivastava, Priyal, Mahalaqua Nazli Khatib, Shilpa Gaidhane, Dipti Shrivastava, Abhay M. Gaidhane, and Quazi Syed Zahiruddin. "Assessment of Mean Platelet Volume (MPV) in Subjects with Type 2 Diabetes Mellitus (T2DM) in a Rural Backdrop of Central India." *MEDICAL SCIENCE* 24, no. 101 (February 2020): 12–21.