ORIGINAL ARTICLE

# Clinical evaluation of *Samshodhana* (*Vamana Karma*) therapy and *Samshamana* (*Pathadi Ghana Vati*) therapy in the management of prediabetes

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## Abstract

**Am:** *Ayurvedic* text vividly described the clinical feature of *Vataja, Pittaja,* and *Kaphaja Prameha,* which indicates the preclinical stage/early stage/subclinical features of diabetes mellitus (DM). Variety of pharmacological and non pharmacological measures have been described for the management of the different kind of *Prameha*/prediabetes with a wide range of lifestyle modification, herbal, mineral, and herbo-mineral formulation for the treatment of *Prameha* including *Madhumeha*. Therefore, the highly evolved description of *Ayurvedic* therapeutics in the line of prevention and management of *Prameha*/prediabetes, it seems to explore the possibilities of developing an *Ayurveda*- inspired line of *Samshodhana* therapy and *Samshamana* therapy in the management of prediabetes and prevention of Type-2 DM for contemporary use today. **Study Design:** The present parallel study was conducted on 60 patients treated with *Samshodhana* (*Vamana* measures) therapy and *Samshamana (Pathadi Ghana Vati)* therapy along with the control group treated with the modern drug (metformin, 500 mg, OD). After completion of trial treatment, the results were statistically analyzed on SPSS 16.0. **Results:** The observation will be made regarding clinical symptomatology, body mass index, fasting blood sugar, and postprandial blood sugar. This study reveals that patients have good improvement, and no unwanted effects were noted at the end of therapy. **Conclusion:** Such type exercise through *Ayurvedic* approach not only provides a new dimension for the management of prediabetics but up to some extent it also checks prediabetics progression to diabetics.

**Key words:** *Madhumeha*, *Panchakarma*, *Prameha*, prediabetes, Type-2 diabetes mellitus, *Vamana Karma*

## INTRODUCTION

*Ayurveda* is one of the major ancient sciences of India. The very fact that it remains a vital health-care system shows its viability and inherent strength. It has imbibed the trends of the times as it evolved through the ages. The aim of *Ayurveda* is two folds, to maintain and promote the health of healthy and to treat the illness of the diseased.[1] For serving these purposes, various health regimens, and treatment modalities have been described. As far as the treatment methods are concerned, *Ayurveda* has described the use of *Samshamana* (palliative treatment) and *Samshodhana* (cellular bio-purification) methods.[2] The latter incorporates the five modes of purification, which include *Vamana* (therapeutic emesis), *Virechana* (therapeutic purgation), *Basti* (therapeutic enemas), *Nasya* (nasal insufflations and instillations) and *Rakta mokshana* (therapeutic bloodletting).[3] These five techniques of bio-purification done through several procedures purify the body system by removing toxic materials from the body. These purification methods are essential components of the curative management of those diseases that are not amenable to palliative management.[3]

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Prediabetes is one of the major clinically entity, which has been vividly described in *Ayurvedic* classics in the context of *Prameha* striking resemblance with the available latest knowledge in this field.[4] Lifestyle and dietary errors are the major etiological categories described for *Prameha*, which is closely resemblance with the etiology of prediabetes. When such clinical condition really established in the body for prolong duration, it may lead to *Madhumeha vis* a *vis* diabetes mellitus (DM). Due to widespread pathogenic involvement, this phase of disease is deeply rooted, and it is difficult to be cure. Prediabetes is also known as early stage of Type-2 DM and it occupying greater significant importance in recent years by the scientific community. Prediabetics are more prone to develop Type-2 DM[5] and its related macro and microvascular complications.[6] Its progression to Type-2 DM is approximately 25% over 3-5 years.[7] The *Ayurvedic* lexicons scientifically conceived three major clinical categories of *Prameha,* namely, *Kaphaja*, *Pittaja*, and *Vataja.* However, if these three clinical stages of *Prameha*/prediabetes are not managed in due time, it may lead to the chronic stage of *Madhumeha*/Type-2 DM. It is the fact that conventional management of prediabetes and Type-2 DM is still not satisfactory. Therefore, the highly evolved description of *Ayurvedic* therapeutics in the line of prevention and management of *Prameha*/prediabetes, it seems to explore the possibilities of developing an *Ayurveda*-inspired line of *Samshodhana (Vamana Karma)* and *Samshamana (Pathadi Ghana Vati)* therapy in the management of prediabetes and prevention of Type-2 DM for contemporary use today. Such type of exercise through *Ayurvedic* approach not only provides a new dimension for the management of prediabetics but up to some extent it also checks prediabetics progression to diabetics.

### Aims and Objectives

1. To study the hypoglycemic effect of *Samshodhana (Vamana Karma)* and *Samshamana (Pathadi Ghana Vati)* therapy on subjective and objectives parameters.
2. To develop *Samshodhana (Vamana Karma)* and *Samshamana (Pathadi Ghana Vati)* therapy as preventive and/or curative measures in prediabetics.

## MATERIALS AND METHODS

### Selection of Cases

A total of 60 cases of prediabetics were selected from OPD and IPD of *Kayachikitsa,* S. S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi after thorough history taking, clinical and laboratory examination and registered irrespective of their age, sex, religion, socio-economic status, etc.

### Type of Study

Comparative parallel clinical study.

### Inclusion Criteria

- Age 30-60 years
- Family history of diabetes, hypertension, dyslipidemia
- Plasma glucose level: Fasting: 100-125 mg/dl
- Postprandial: 140-199 mg/dl
- HbA1C: 5.7-6.4%.

### Exclusion Criteria

- Age <30 years and >60 years
- Type-II DM (NIDDM) with and without complications
- Type-I DM (IDDM) associated with and without complications
- Diabetes due to endocrinopathies, for example, pheochromocytoma, acromegaly, cushing's syndrome, hyperthyroidism, etc.
- Drug or chemical-induced DM, for example, glucocorticoids, thyroid hormone, thiazides, phenytoin, etc.
- Certain genetic syndromes sometimes associated with DM, e.g., Down's syndrome, Klinefelter's syndrome, Turner's syndrome, etc.

### Termination Criteria

Sudden deterioration in patient's health status during the period of study.

- Non compliance of the patient.

### Study Design and Treatment Schedule

All the 60 patients after ethical approval from Ethical Committee of Institute of Medical Sciences, Banaras Hindu University were recruited into three groups based on given advice. Out of 60 prediabetic patients, 8 patients were dropped out (5 patients from Group-I and 3 patients from Group-II).

Group-I: 30 registered cases were recommended both *Vamana* therapy and *Pathadi Ghana Vati* drug.

Group-II: 30 registered cases were advised for control group i.e., treated with modern drug (metformin 500 mg OD) on Doctor's prescription.

### Details of Procedure and Methods Proposed to be Used in the Study

#### *Preperation of drug*

The *Panchanga* of *Patha, Murva, and Shvadanshtra* were procured from the market and authenticated by *Ayurvedic* experts. The *Panchanga* was dried and powdered, extracted in aqueous and the yield was recorded. The extract of the compound drug was made as *Ghana Vati*.

30 patients fulfilling the criteria for of *Vamana Karma* and *Pathadi Ghana Vati* were treated in this group. Before *Vamana Karma* patients were specially examined for electrocardiogram, chest X-ray, and other systemic examination for suitability of *Vamana Karma*.

### *Preparation of patients*

The patients of prediabetes ready to undergo *Vamana* therapy, the outset were prepared with *Snehana* and *Svedana karma*.

### Abhyantara Snehapana

For *Snehapana,* 30 ml *Go-Ghrita* was given at 7.00 am on empty stomach. On the basis of this test dose, *Go-Ghrita* was gradually increased by 30 ml/day. After administering *Ghrita*, instructions were given to the patient not to take any type of food, until he feels hunger, and only hot water was allowed to drunk. When patients were felt hunger, light diet was prescribed mainly *Chapati* of wheat along with some vegetables or *Dala* at the day time. In the evening, mainly *Khichadi* was prescribed.

### Abhyanga and Svedana

After ascertaining *Samyaka Snehana*, patients were subjected to *Abhyanga* and *Vashpa Sveda*. In the morning (at about 10 am) and in the evening (at about 4.30 pm) of the gap day, i.e., the day after the day of completion of *Snehapana*. *Abhyanga* to the whole body was done for about 30 min in all the positions. For this purpose, warm *Narayana Taila* was used. Thereafter, *Vashpa Sveda* of 30 min was given to the whole up to profuse perspiration. The further patient was advised to sit on the chair for about 15 min. Thereafter, instruction was given to go to the bed covered with a blanket and not to move in the open area.

### Diet the Evening of Gap Day

In the evening of gap day, *Kapha Vardhaka* diet was given, special *Krishara* (*Khichadi*) made of about 50 g each of rice and *Maasha* (*Urada Dala*), 25 g of each *Taila,* and *Ghrita* was given along with 250 g of curd. The salt was added as per requirement.

### *Vamana Karma*

After *Samyaka Svedana, the* patient was shifted to *Vamana* chair where he/she was given 200 ml milk. After 5 min, the mixture of *Madanphala*, *Vacha Churna*, *Madhu,* and *Saindhava* mixed in the quantity of 6 g, 2 g, 20 g, and 1.5 g, respectively and it was given orally. After 10 min, full stomach milk was given orally and waits for next 10 min and observed the pre features of *Vamana Karma,* i.e., Horripilation and Nauseant feeling. The therapeutic emesis was started within 10 min. Intake of full stomach milk and *Vamana Vega* was noted at every step.

During the *Vega,* the patient was helped by an attendant, pressing the abdomen with palms. In between of two *Vega*, the back of the patient was gently massaged in upward direction. When *Pitta* in vomitus was seen, 2 L saline hot water was given for emesis. During this procedure after each *Vega*, pulse and blood pressure were monitored time to time.

After completion of *Vamana, Karma* patient was transferred to the bed where again pulse, blood pressure, and respiration were noted. In the room, *Dhumpana* was done by *Nirdosha Ayurvedic* Cigarette, and patient was kept in keen observation for the whole day.[8,9]

### *Samsarjana Karma*

Depend on the type of *Shuddhi* (*Pravara*, *Madhyama,* and *Avara*); *Samsarjana Krama* was followed. In case of *Avara*, *Madhyama,* and *Pravara Shuddhi, Peya, Vilepi, Mudga Yusha,* and rice with *Mudga Yusha* were given for one meal time, two meal times, and three meal times, respectively from the evening of *Vamana* day for 3, 5, and 7 days, respectively.

Patients were instructed that this diet was taken as per appetite. *Peya* and *Vilepi* were prepared from 50 g of the rice as per standard methods. *Mudga Yusha* was obtained by cooking 50 g of *Mudga* in the required quantity of water. In the last, *Odana* (rice) prepared from 50 g of rice along with *Mudga Yusha* (prepared from 50 g of *Mudga*).[8,9]

All the patients were advised to take normal diet and life style, which they were routinely performed.

### Assessment Criteria

The assessment of the treatment was based on both subjective and objective parameters.

### *Subjective assessment*

To assess the subjective features of prediabetics, the clinical symptomatology was graded into four grades (0-3) scale on the basis of severity and duration. The changes in the gradations of each symptoms such as polyuria *(Atimutrata),* polydipsia *(Atitrishna),* polyphagia *(Atikshudha),* Numbness in hands and feet *(Hastha-Pada Shuunyata),* burning sensation in hands and feet *(Hastha-Pada Daha),* excessive sweating *(Atisveda),* laziness *(Alasya),* excessive sleep *(Atinidra),* and flabbiness of the body *(Shithilangata)* were noted on a prepared protocol to assess the therapeutic response of trial treatment.

Following symptoms such as *Mukha Shosha* (dryness in the mouth) and *Sheeta Priyata* (liking of cold things) were assessed on the basis of their absence and presence.

Grade 0: Absent

i: Present

Besides this, the degree of improvement was analyzed on the basis of clinical gradations of symptoms were as follows.

0: Completely relieved.
1: Mild symptoms present.
2: Moderate symptoms present
3: Severe symptoms present.

ii. Objective assessment

Objective assessment was done on the following basis:

- Body mass index (BMI)
- Fasting blood glucose
- Postprandial blood glucose.

## Results and Observations

The study shows the incidence of age and sex of 60 patients of prediabetes revealed that the registered patients were fall in the age range between 30 and 60 years. The sex incidence in 40 cases, the greater number of patients were male, i.e., 47 (78.33%) followed by female 13 (21.67%).

## Clinical Symptomatology

In Group-I, incidence of clinical symptomatology in 60 patients of prediabetes revealed that the maximum number of patients (76.6%) had polyurea followed by laziness (70%), polydipsia and burning sensation (66.6%), dryness in mouth (60%), polyphagia (56.7%), excessive sweating (53.3%), excessive sleep (50%), flabbiness (40%), liking of cold things (20%), and numbness (6.7%) [Table 1].

In Group-II, incidence of clinical symptomatology in 60 patients of prediabetes revealed that the maximum number of patients (73.4%) had laziness followed by polyurea and polyphagia (60%), dryness in mouth (53.4%), polydipsia/ burning sensation/excessive sleep (50%), excessive sweating (33.3%), flabbiness (30%), liking of cold things (13.3%), and numbness (6.7%) [Table 1].

## Effect of Trial Treatment on Clinical Symptomatology of Prediabetes

The study shows the significant shift of grades of polyurea in different trial groups; it was statistically highly significant ($P < 0.001, \chi^2 = 38.00$) in Group-I, while in Group-II, the shift of grade was statistically highly significant ($P < 0.001, \chi^2 = 23.967$) after 3 years of trial treatment. On polydipsia, it was statistically highly significant in Group-I ($P < 0.001$, $\chi^2 = 32.310$) while in Group-II, the shift of grade was statistically significant ($P < 0.05$, $\chi^2 = 14.130$) after 3 years of trial observation. On polyphagia, it was statistically highly significant ($P < 0.001$, $\chi^2 = 20.599$) in Group-I while in Group-II, the shift of grade was statistically significant ($P < 0.05$, $\chi^2 = 12.174$). On numbness in hands and feet, it was statistically insignificant ($P > 0.05, \chi^2 = 6.000$) in both Group-I and Group-II ($P > 0.05$, $\chi^2 = 4.714$). On burning sensation in different trial groups, it was statistically highly significant ($P < 0.001$, $\chi^2 = 38.906$) in Group-I and Group-II ($P < 0.001$, $\chi^2 = 31.312$) both. On Excessive Sweating, the shift of grade was statistically highly significant ($P < 0.001$, $\chi^2 = 18.268$) in Group-I and statistically significant ($P < 0.05$, $\chi^2 = 10.814$) in Group-II. On laziness, it was statistically highly significant ($P < 0.001$, $\chi^2 = 34.052$) in Group-I and also statistically highly significant ($P < 0.001$, $\chi^2 = 30.574$) in Group-II. On excessive sleep, it was statistically highly significant ($P < 0.001, \chi^2 = 29.100$) in Group-I and also statistically highly significant ($P < 0.001$, $\chi^2 = 22.606$) in Group-II. On flabbiness, the shift of grade was statistically highly significant ($P < 0.001, \chi^2 = 16.154$) in Group-I while it was statistically highly significant ($P < 0.001$, $\chi^2 = 22.082$) in Group-II. On dryness in the mouth, the study shows the significant shift of grades in different trial groups;

**Table 1:** Incidence of clinical symptomatology in 60 cases of prediabetes

| Presence of symptoms initially | Number of patients and percentage | | | |
|---|---|---|---|---|
| | Group-I | Group-II | Group-III | Group-IV |
| Polyuria | 20 (66.6) | 23 (76.7) | 23 (76.6) | 18 (60) |
| Polydipsia | 17 (56.6) | 21 (70) | 20 (66.6) | 15 (50) |
| Polyphagia | 19 (63.4) | 19 (63.3) | 17 (56.7) | 18 (60) |
| Numbness | 1 (3.3) | 1 (3.3) | 2 (6.7) | 2 (6.7) |
| Burning sensation | 16 (53.3) | 5 (16.7) | 20 (66.6) | 15 (50) |
| Excessive sweating | 14 (46.7) | 13 (43.4) | 16 (53.3) | 10 (33.3) |
| Laziness | 27 (90) | 27 (90) | 21 (70) | 22 (73.4) |
| Excessive sleep | 15 (50) | 23 (79.6) | 15 (50) | 15 (50) |
| Flabbiness | 10 (33.3) | 10 (33.4) | 12 (40) | 9 (30) |
| Dryness in mouth | 19 (63.3) | 15 (50) | 18 (60) | 16 (53.4) |
| Liking of cold things | 6 (20) | 7 (23.3) | 6 (20) | 4 (13.3) |

it was statistically highly significant ($P < 0.001$, $\chi^2 = 32.618$) in Group-I and also statistically highly significant ($P < 0.001$, $\chi^2 = 23.041$) in Group-II. On liking of cold things, shift of grade was statistically significant ($P < 0.05$, $\chi^2 = 9.923$) in Group-I and also statistically significant ($P < 0.05$, $\chi^2 = 9.429$) in Group-II [Tables 2-12]. On the basis of Chi-square test, between the group comparison, the differences were statistically not significant ($P > 0.05$) in any group.

**Table 2:** Effect on polyurea

| Groups | Number of cases (%) | | | | | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| | Grade | BT | F1 | F2 | F3 | |
| Group-I (*n*=25) | 0 | 7 (23.3) | 13 (44.8) | 4 (13.3) | 23 (92) | $\chi^2$=38.00 *P*<0.001 HS |
| | 1 | 16 (53.3) | 16 (55.2) | 16 (53.3) | 2 (8) | |
| | 2 | 7 (23.3) | 0 (0.0) | 9 (30) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 1 (3.3) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 12 (40) | 13 (43.3) | 1 (3.3) | 19 (70.4) | $\chi^2$=23.967 *P*<0.001 HS |
| | 1 | 15 (50) | 14 (46.7) | 19 (63.3) | 8 (29.6) | |
| | 2 | 3 (10) | 3 (10) | 10 (33.3) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=4.682 *P*>0.05 NS | $\chi^2$=4.382 *P*>0.05 NS | $\chi^2$=6.399 *P*>0.05 NS | $\chi^2$=5.771 *P*>0.05 NS | |

**Table 3:** Effect on polydipsia

| Groups | Number of cases (%) | | | | | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| | Grade | BT | F1 | F2 | F3 | |
| Group-I (*n*=25) | 0 | 10 (33.3) | 21 (72.4) | 17 (65.4) | 22 (88.0) | $\chi^2$=32.310 *P*<0.001 HS |
| | 1 | 16 (53.3) | 6 (20.7) | 9 (34.6) | 3 (12) | |
| | 2 | 4 (13.3) | 2 (6.9) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 15 (50) | 21 (70) | 19 (65.5) | 19 (70.4) | $\chi^2$=14.130 *P*<0.05 S |
| | 1 | 12 (40) | 7 (23.3) | 10 (34.5) | 8 (29.6) | |
| | 2 | 3 (10) | 2 (6.7) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=3.726 *P*>0.05 NS | $\chi^2$=4.159 *P*>0.05 NS | $\chi^2$=0.056 *P*>0.05 NS | $\chi^2$=3.534 *P*>0.05 NS | |

**Table 4:** Effect on polyphagia

| Groups | Number of cases (%) | | | | | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| | Grade | BT | F1 | F2 | F3 | |
| Group-I (*n*=25) | 0 | 13 (43.3) | 13 (44.8) | 18 (69.2) | 21 (84) | $\chi^2$=20.559 *P*<0.001 HS |
| | 1 | 12 (40) | 13 (44.8) | 8 (30.8) | 4 (16) | |
| | 2 | 5 (16.7) | 3 (10.3) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 12 (40) | 14 (46.7) | 17 (58.6) | 19 (70.4) | $\chi^2$=12.174 *P*<0.05 S |
| | 1 | 15 (50) | 13 (43.3) | 12 (41.4) | 8 (29.6) | |
| | 2 | 3 (10) | 3 (10) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-sqwuare test | | $\chi^2$=1.848 *P*>0.05 NS | $\chi^2$=4.382 *P*>0.05 NS | $\chi^2$=6.399 *P*>0.05 NS | $\chi^2$=5.771 *P*>0.05 NS | |

**Table 5:** Effect on numbness in hands and feet

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 28 (93.3) | 29 (100) | 26 (100) | 25 (100) | $\chi^2$=6.000 *P*>0.05 NS |
| | 1 | 2 (6.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 28 (93.3) | 29 (96.7) | 29 (100) | 27 (100) | $\chi^2$=4.714 *P*>0.05 NS |
| | 1 | 2 (6.7) | 1 (3.3) | 0 (0.0) | 0 (0.0) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=0.702 *P*>0.05 NS | $\chi^2$=2.858 *P*>0.05 NS | $\chi^2$=0.0 *P*=0.0 NS | $\chi^2$=0 *P*=0 NS | |

**Table 6:** Effec on burning sensation

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 10 (33.3) | 14 (48.3) | 20 (76.9) | 25 (100) | $\chi^2$=38.906 *P*<0.001 HS |
| | 1 | 13 (43.3) | 14 (48.3) | 6 (23.1) | 0 (0.0) | |
| | 2 | 7 (23.3) | 1 (3.4) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 15 (50) | 16 (53.3) | 24 (82.8) | 24 (88.9) | $\chi^2$=31.312 *P*<0.001 HS |
| | 1 | 10 (33.3) | 12 (40) | 5 (17.2) | 3 (11.1) | |
| | 2 | 5 (16.7) | 2 (6.7) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=17.543 *P*<0.05 S | $\chi^2$=16.207 *P*<0.05 S | $\chi^2$=2.956 *P*>0.05 NS | $\chi^2$=6.465 *P*>0.05 NS | |

**Table 7:** Effect on excessive sweating

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 14 (46.7) | 20 (69) | 23 (88.5) | 22 (88) | $\chi^2$=18.268 *P*<0.001 HS |
| | 1 | 13 (43.3) | 9 (31) | 3 (11.5) | 3 (12) | |
| | 2 | 3 (10) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 20 (66.7) | 23 (76.7) | 26 (89.6) | 24 (88.9) | $\chi^2$=10.814 *P*<0.05 S |
| | 1 | 10 (33.3) | 7 (23.3) | 3 (10.3) | 3 (11.1) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=7.353 *P*>0.0 NS | $\chi^2$=0.729 *P*>0.05 NS | $\chi^2$=1.125 *P*>0.05 NS | $\chi^2$=0.522 *P*>0.05 NS | |

**Table 8:** Effect on laziness

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 9 (30) | 14 (48.3) | 22 (84.6) | 24 (96) | $\chi^2$=34.052 *P*<0.001 HS |
| | 1 | 17 (56.7) | 13 (44.8) | 4 (15.4) | 1 (4) | |
| | 2 | 4 (13.3) | 2 (6.9) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 8 (26.7) | 16 (53.3) | 21 (72.4) | 21 (77.8) | $\chi^2$=30.574 *P*<0.001 HS |
| | 1 | 17 (56.7) | 12 (40) | 8 (27.6) | 6 (22.2) | |
| | 2 | 5 (16.7) | 2 (6.7) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=6.937 *P*>0.05 NS | $\chi^2$=0.941 *P*>0.05 NS | $\chi^2$=3.347 *P*>0.05 NS | $\chi^2$=4.042 *P*>0.05 NS | |

**Table 9:** Effect on excessive sleep

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 15 (50) | 20 (69) | 25 (96.2) | 25 (100) | $\chi^2$=29.100 *P*<0.001 HS |
| | 1 | 13 (43.3) | 9 (31) | 1 (3.8) | 0 (0.0) | |
| | 2 | 2 (6.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 15 (50) | 20 (66.7) | 24 (82.8) | 23 (85.2) | $\chi^2$=22.606 *P*<0.001 HS |
| | 1 | 13 (43.3) | 10 (33.3) | 5 (17.2) | 4 (14.8) | |
| | 2 | 2 (6.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=6.754 *P*>0.05 NS | $\chi^2$=0.187 *P*>0.05 NS | $\chi^2$=3.162 *P*>0.05 NS | $\chi^2$=3.865 *P*>0.05 NS | |

**Table 10:** Effect on flabbiness of the body

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 18 (60) | 25 (86.2) | 24 (92.3) | 25 (100) | $\chi^2$=16.154 *P*<0.001 HS |
| | 1 | 12 (40) | 4 (13.8) | 2 (7.7) | 0 (0.0) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 21 (70) | 27 (90) | 28 (96.6) | 27 (100) | $\chi^2$=22.082 *P*<0.001 HS |
| | 1 | 8 (26.7) | 3 (10) | 1 (3.4) | 0 (0.0) | |
| | 2 | 1 (3.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=5.065 *P*>0.05 NS | $\chi^2$=0.799 *P*>0.05 NS | $\chi^2$=0.797 *P*>0.05 NS | $\chi^2$=0 *P*=0 NS | |

## Effect of Trial Treatment on Laboratory Parameters

### *BMI*

The BMI study shows that the initial mean and SD for Group-I was 26.44 ± 4.093 which decreased to 24.57 ± 3.427 after trial treatment; the result was statistically highly significant ($P < 0.001$). In Group-II, the mean was decreased from 24.63 ± 2.194 to 24.53 ± 1.768 showing statistically insignificant result ($P > 0.05$). The difference in means was highest in Group-I (1.638) followed by Group-II (0.146) [Table 13].

**Table 11:** Effect on dryness in mouth

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 12 (40) | 19 (65.5) | 26 (100) | 22 (88) | $\chi^2$=32.618 *P*<0.001 HS |
| | 1 | 16 (53.3) | 10 (34.5) | 0 (0.0) | 3 (12) | |
| | 2 | 2 (6.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 14 (46.7) | 18 (60) | 26 (89.7) | 22 (81.5) | $\chi^2$=23.041 *P*<0.00 HS |
| | 1 | 14 (46.7) | 12 (40) | 3 (10.3) | 5 (18.5) | |
| | 2 | 2 (6.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=2.036 *P*>0.05 NS | $\chi^2$=3.492 *P*>0.05 NS | $\chi^2$=3.403 *P*>0.05 NS | $\chi^2$=2.625 *P*>0.05 NS | |

**Table 12:** Effect on liking of cold things

| Groups | Grade | Number of cases (%) BT | F1 | F2 | F3 | Within the group comparison (Friedman test) |
|---|---|---|---|---|---|---|
| Group-I (*n*=25) | 0 | 24 (80) | 28 (96.6) | 26 (100) | 25 (100) | $\chi^2$=9.923 *P*<0.05 S |
| | 1 | 6 (20) | 1 (3.4) | 0 (0.0) | 0 (0.0) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Group-II (*n*=27) | 0 | 26 (86.7) | 28 (93.3) | 29 (100) | 27 (100) | $\chi^2$=9.429 *P*<0.05 S |
| | 1 | 4 (13.3) | 2 (7.7) | 0 (0.0) | 0 (0.0) | |
| | 2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| | 3 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | |
| Between the group comparison, Chi-square test | | $\chi^2$=1.022 *P*>0.05 NS | $\chi^2$=1.958 *P*>0.05 NS | $\chi^2$=0 *P*=0 NS | $\chi^2$=0 *P*=0 NS | |

**Table 13:** Effect of treatment on BMI (*n*=60)

| Groups | BMI (mean±SD) BT | AT | Within the group comparison, paired *t*-test, (BT-AT) |
|---|---|---|---|
| Group-I (*n*=25) | 26.44±4.093 | 24.57±3.427 | 1.638±1.403, *t*=5.839, *P*<0.001, HS |
| Group-II (*n*=27) | 24.63±2.194 | 24.53±1.768 | 0.146±1.236, *t*=0.614, *P*>0.05, NS |
| Between the group comparison, one-way ANOVA | *F*=3.251 *P*<0.05 S | *F*=1.803 *P*>0.05 NS | |
| *Post-hoc* test (Bonferroni), Significant pairs (*P*<0.05) | - | - | |

BMI: Body mass index, SD: Standard deviation

### *Fasting blood sugar (FBS)*

The blood sugar fasting in Group-I, the initial mean ± SD. was 114.46 ± 7.154 which reduced to 97.44 ± 14.023 after complete follow-up, the improvement was statistically highly significant ($P < 0.001$). While in Group-II, the initial mean ± SD 112.60 ± 8.253 reduced to 100.03 ± 10.979, this fall was also statistically highly significant ($P < 0.001$). The reduction in means was highest in Group-I (17.576) followed by Group-II (12.233) [Table 14].

### *Postprandial blood sugar (PPBS)*

The PPBS estimations in Group-I, the initial mean ± SD was 174.02 ± 16.232 which decreased to 137.46 ± 12.078 after 3rd follow-up, the reduction was statistically highly significant ($P < 0.001$). While in Group-II, the initial mean ± SD was 175.32 ± 15.295 decreased to 143.33 ± 17.136, it was also statistically highly significant ($P < 0.001$). The difference in means was highest in Group-I (38.800) followed by Group-II (31.856) [Table 15].

**Table 14:** Effect on BSF (*n*=60)

| Groups | BSF (mean±SD) | | | | Within the group comparison, paired '*t*' test, (BT-FU3) |
|---|---|---|---|---|---|
| | BT | FU1 | FU2 | FU3 | |
| Group-I (*n*=25) | 114.46±7.154 | 106.66±6.601 | 101.89±8.831 | 97.44±14.023 | 17.576±13.327, *t*=6.594, *P*<0.001, HS |
| Group-II (*n*=27) | 112.60±8.25 | 107.47±6.35 | 103.64±7.22 | 100.03±10.97 | 12.233±10.026, *t*=6.340, *P*<0.001, HS |
| Between the group comparison, one-way ANOVA | *F*=0.499 *P*>0.05 NS | *F*=0.358 *P*>0.05 NS | *F*=0.660 *P*>0.05 NS | *F*=0.917 *P*>0.05 NS | |
| *Post-hoc* test (Bonferroni), Significant pairs (*P*<0.05) | - | - | - | - | |

BSF: Blood sugar fasting, SD: Standard deviation

**Table 15:** Effect on BSPP (*n*=60)

| Groups | BSPP mean±SD | | | | Within the group comparison, paired *t*-test, (BT-FU3) |
|---|---|---|---|---|---|
| | BT | FU1 | FU2 | FU3 | |
| Group-I (*n*=25) | 174.02±16.232 | 156.41±15.829 | 148.61±12.677 | 137.46±12.078 | 38.800±16.496, *t*=11.761, *P*<0.001, HS |
| Group-II (*n*=27) | 175.32±15.295 | 157.87±20.575 | 149.67±20.133 | 143.33±17.136 | 31.856±16.415, *t*=10.04, *P*<0.001, HS |
| Between the group comparison, one-way ANOVA | *F*=0.078 *P*>0.05 NS | *F*=0.762 *P*>0.05 NS | *F*=2.036 *P*>0.05 NS | *F*=3.303 *P*<0.05 S | |
| *Post-hoc* test (Bonferroni), Significant pairs (*P*<0.05) | - | - | - | - | |

BSPP: Blood sugar postprandial, SD: Standard deviation

**Table 16:** Mean percentage fall in FBS and PPBS in different trial group

| Group | Percentage fall in FBS | Percentage fall in PPBS |
|---|---|---|
| I | 15.36 | 22.30 |
| II | 10.86 | 18.17 |

FBS: Fasting blood sugar, PPBS: Postprandial blood sugar

### *Mean percentage fall in FBS and PPBS in different trial group*

The Group-I (*Samshodhana* + *Samshamana* therapy) shows maximum fall (15.36%) in FBS level followed by Group-II (control group) (10.86%). The rate of fall in PPBS in Group-I was maximum (22.30%) followed by Group-II (18.17%) [Table 16].

## DISCUSSION

Prediabetes is a serious medical condition, and it is the early stage of Type-2 DM. Such types of patients are at risk for not only developing Type-2 DM but also risk for macro- and micro-vascular complications.[5,6] The progression into DM from prediabetes is approximately 25% over 3-5 years.[7] The prediabetes is widely recognized as an early stage of DM, and it imparts variety of metabolic disorders. The available therapeutic modalities in the conventional system of medicine are not up to the mark for talking the cases of prediabetes to the normal one. Besides this, it also has unwanted effects and in due course of time, it may lead to DM and other life-threatening consequences.

The BMI reveals that patients of Group-III, i.e., *Samshodhana (Vamana Karma),* and *Samshamana (Pathadi Ghana Vati)* therapy shows a greater reduction of BMI (1.638) while least reduction was observed in modern medicine treated Group-IV (0.146). The selected *Samshodhana* and *Samshamana* measures (Group-III) have shown significant hypoglycemic effect regarding reducing FBS by 15.36% and PPBS by 22.30%. Where in control group (Group-IV), least reduction was observed regarding reducing FBS by 10.86% and PPBS by 18.17%. This signifies *Samshodhana* and *Samshamana* measures play a significant role in the management of prediabetes and prevention of Type-2 DM. Besides, this study also indicates that if biopurificatory measures are applied in due concentration, it will not only check the gradual increase of BMI but helps in the management of prediabetes. Side by side, it also checks the precipitating factors which play a significant role in the pathophysiology of obesity, prediabetes, DM, and metabolic syndrome such as- *Amas*,

*Malas*, and vitiated *Doshas*. This signifies that for attaining better response, both therapies (*Samshodhana* + *Samshamana* therapy) incorporate together in the prediabetics.

An effort was made to analyze the lipid profile in this series but except serum cholesterol and TG, rest other variants of lipid profile did not show significant improvement during treatment. This study signifies that both biopruificatory measures and *Samshamana* measures may be subjected jointly for a better therapeutic response.

In this study, the selected *Samshodhana* measures and *Samshamana* measures not only have encouraging results regarding metabolic correction but also seems to be helpful to improve overall wellbeing in Prediabetes. Side by side, it is also found safe regarding renal, hepatic, hematological, and cardiac protection point of view because their values were fluctuated within the normal at before treatment (BT) and after treatment (AT). Besides, this studies also overview that if *Samshodhana* measures and *Samshamana* measures are jointly applying in Prediabetes, it will sure to normalizes the blood sugar and also cut off its progression to Type-2 DM. Thus, these two approaches of *Ayurvedic* classics have significant preventive and curative role in Type-2 DM and prediabetes, respectively.

## CONCLUSION

It seems that issues depicted above can be tackled with the holistic approach of *Ayurvedic* therapeutics by utilizing the package of *Samshamana* measures and bio-purificatory measures of *Ayurveda*, which may not only control the lipid and sugar metabolism in the system but also control its progression to Type-2 DM. The *Samshodhana* therapy (cellular biopurificatory measures) of *Ayurveda* is claimed to produce a cellular cleansing effect, promoting mobilization of essential nutritional pool, and immune enhancing effect. Such a line of management is preferred in *Ayurveda* because of *Srotodusti* and accumulation of metabolic waste products (*Ama*) are the main culprit in the diathesis of disease, which is of great significance in the case of prediabetes and DM.

This study reveals that *Samshodhana* measures and *Samshamana* measures have shown a significant reduction in FBS and PPBS, besides noticeable trends of lipid correction. The approach used in this study seems to be effective and completely safe because no unwanted effects were noted during the 3 years trial periods. Thus, on the basis of observations made in the present study, it can be concluded that prediabetes was well-known disease entity since antiquity. The conventional management of prediabetes is still not very satisfactory, and the current strategy of prevention and treatment of prediabetes is rapidly changing. This study had been undertaken with the same perspective.

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