

Efficacy of *Vamana Karma* (therapeutic emesis) followed by *Darvyadi Kwatha* (herbal decoction) in the management of prediabetes (*Prameha*) - A single-arm clinical trial

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Abstract

Background: Prediabetes is an alarming condition to control and prevent from developing diabetes mellitus which occurs due to the change in lifestyle and food habits. Timely untreated prediabetes turn into type-2 diabetes mellitus within a year and systemic complications such as retinopathy, nephropathy, and neuropathy could occur and in later stage multi system damage could take place. **Aims:** The aim of this study is to evaluate the efficacy of *Vamana Karma* (therapeutic emesis) with *Ikshuvaku Yoga* and followed by oral administration of *Darvyadi Kwatha* (herbal decoction) in the management of prediabetes. **Materials and methods:** After approval of IEC and registration under clinical trial registry of India, 20 patients suffering from prediabetes were registered in the trial. Diagnosis criteria were hemoglobin A1c (HbA1c), fasting blood sugar (FBS) and postprandial blood sugar (PPBS), and assessment criteria includes HbA1c, FBS, PPBS, along with improvement in *Agnibala* (strength of digestion and metabolism), *Dehabala* (physical strength) and *Satvabala* (mental strength), relief sign and symptom of prediabetes (*Prameha*), and improvement in quality of life (SF-36 Score). Classical *Vamana Karma* followed by oral administration of *Darvyadi Kwatha* was done. Total duration of treatment was 45 days and last follow-up was done on the 120th day. Student's *t*-test was used for the analysis of parametric data. **Results:** After the treatment were observed that there is improvement in subjective as well as in objective parameters. Statistically highly significant result was observed in HbA1c (BT [day 0] Mean score 6.25 and AT [day 120] 5.63 [$P < 0.001$]), FBS (BT [day 0] mean score 120.05 and AT [day 120] 93.31 [$P < 0.001$]) and PPBS (BT [day 0] mean score 165.26 and AT [day 120] 112.84 [$P < 0.001$]), sign and symptoms of *Prameha*, *Dehabala*, *Agnibala*, *Satvabala*, and quality of life (SF-36 Score). **Conclusion:** The present clinical study concludes that therapeutic emesis (bio purification) followed by *Darvyadi Kwatha* as internal medicine shows significant result in treating prediabetes (*Prameha*) safely and effectively also control and prevent developing diabetes mellitus. None of the patient converted to diabetes mellitus on the day 120.

Keywords: *Darvyadi Kwatha*, *Prameha*, prediabetes, *Vamana Karma*

Introduction

Prediabetes as a state of intermediate hyperglycemia using three specific parameters, fasting blood sugar (FBS) level 100–125 mg/dl, postprandial blood sugar level between 140 and 200 mg/dl and hemoglobin A1c (HbA1c) level of 5.7% to 6.4% for the definition of prediabetes.^[1] The WHO estimates that diabetes was the seventh leading cause of death in 2016. The global diabetes prevalence in 2019 was estimated to be 9.3% (463 million people), rising to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045.^[2] Prediabetes is the metabolic disorder can be compared with *Prameha* based on the clinical signs and symptoms of prediabetes it has a close resemblance to the disease *Prameha* described in *Ayurveda*.^[3]

A clinical condition characterized by excessive turbid urination is broadly termed as *Prameha*, which is further classified into twenty subtypes based on the involvement of *Dosha* and presentation of urine, all the *Prameha* in due course of time converts into *Madhumeha* (diabetes mellitus). The

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management of type-2 diabetes mellitus (T2DM) includes oral hypoglycemic drugs and insulin in the later stage. On one side, condition deteriorates due to side effects of medication and on another side due to complications of T2DM itself. The entire globe is searching for safe and effective treatment for preventing and controlling T2DM. *Prameha* is a disease caused due to *Mandagni* (~low digestive fire and metabolism), *Bahudosha* (excessive *Dosha*), *Bahudravashleshma* (*Kapha* with increase liquidity), and *Abaddhameda* (increased triglyceride and bad cholesterol) along with an increase of *Kleda* (excessive fluidity) in the body, all of which belongs to the group of *Kapha* substance in the body.^[4] Hence, *Samshodhana* (*Vamana*)^[5] treatment is one of the best remedies for correcting *Agni* (digestive fire)^[6] and elimination of *Bahudosha*. Further *Vamanakarma* is the best treatment specifically for the elimination of excessive *Kapha* and related substances like *Kleda* and to reduce *Abaddhameda* from the body. *Darvyadi Kwatha*, especially indicated in all kinds of diabetes by Acharya Charaka.^[7] Hence, *Vamana Karma*^[8] followed by oral administration of *Darvyadi Kwatha* was selected for the treatment of prediabetes.

Materials and methods

Ethics

After getting approval from the Ethics Committee (AIIA/2018/PG-73), the trial was registered in central trial registry – India (CTRI/2019/03/017952), it was registered prospectively. Informed consent was obtained from all enrolled individuals on clinical trial.

Participants

After screening 39 patients, 20 patients were enrolled for schedule of 15 days classical *Vamana Karma* with *Ikshvaku Yoga*^[9] followed by the oral administration of *Darvyadi Kwatha* in the dose of 80 ml twice a day before food for 1 month.

Inclusion criteria

Age between 30 years and 60 years, obese patients, HBA1_C between 5.7% and 6.4%, FBS level between 100 and 125 mg/dl and body mass index >25.

Exclusion criteria

Insulin-dependent diabetes mellitus patients, gestational diabetes, patients on steroids or oral hypoglycemic drugs, malignant and accelerated hypertension, CCF, pregnant women, and lactating mother suffering with any serious disease condition.

Diagnostic criteria

Thirty-eight patients screened and 20 patients were registered for the study. HBA1_C between 5.7% and 6.4%, fasting plasma glucose 100 mg/dl–125 mg/dl, and postprandial blood glucose 140 mg/dl–200 mg/dl.

Intervention

Vamana Karma was planned for patients on inpatient department basis. *Deepana* (appetizers) and *Pachana* (carminatives)^[10] were started with *Nagarmotha Churna* (*Cyperus Rotundus L.*)^[11] 3 g twice a day before food and *Panchakola Churna* (*Pippali* [*Piper Longum L.*], *Pippalimoola* [*Root of Piper longum L.*], *Chavya* [*Piper Retrofractum Vahl.*], *Chitraka* [*Plumbago Zeylanica L.*] and *Shunthi* [*Zingiber Officinale Roscoe.*])^[12] Three gram twice a day after food for 3 days. Then, *Snehapana* (internal oleation)^[13] was done with *Murchhita Ghrita* (a medicated ghee)^[14] for 5 days in increasing dose. After that *Sarvanga Abhyanga* (external oleation)^[15] and *Vashpa Swedana* (whole body steam)^[16] were done with *Tila Taila* (sesame oil) and *Dashmoola Kwatha* (decoction of ten roots), respectively, for 2 days. *Vamana Karma* was done with classical *Ikshvaku Yoga* (*Madhuyashti Kashaya Yoga*). On the day of *Vamana Karma*, patients after confirming digestion of previously taken food, vitals were measured and given *Akanthpana* with *Ksheer* (milk). Then *Vamaka* drugs were given with *Ikshvaku Yoga* and waited for one *Muhurta* (48 min). If within one *Muhurta* *Vamana* is started, then it was continued with *Madhuyashti Phanta*^[17] until *Pittanta Darshana* as per strength of the patient. After that *Lavnodaka* was given until *Samyaka Lakshana* (appropriate symptoms) of *Vamana Karma* were observed and vitals were measured frequently.^[18] *Samsarjana Karma* (special dietetic regimen) was given for 5 days, followed by the oral administration of *Darvyadi Kwatha* 80 ml twice a day before food to the patients for 30 days [Table 1].

Table 1: Proposed therapeutic procedures, drugs doses, and time schedule

Procedure	Duration (days)	Medicine	Dose	Time
<i>Deepana</i> (appetizer) and <i>Pachana</i> (carminatives)	3	<i>Nagarmotha Churna</i> <i>Panchakola Churna</i>	3 g 3 g	TDS
<i>Snehapana</i> (medicated oleation therapy)	5	<i>Murchhita Ghrita</i>	Increasing	6 am-8 am
<i>Abhyanga</i> (whole body massage by medicated oil)	2	<i>Tila Taila</i>	100 mL	After <i>Snehapana</i>
<i>Vashpa swedana</i> (whole body steam)	2	<i>Dashmoola Kwatha</i>	As per requirement	After <i>Abhyanga</i>
<i>Vamana Karma</i> (therapeutic emesis)	1	<i>Ikshvaku Yoga</i> (<i>Ikshvaku</i> , <i>Madhu</i> , <i>Saindhav</i> and <i>Yashtimadhu Phant</i>)		After sunrise 6 am-8 am
<i>Sansarjana Krama</i> (specific diet regimen)	5	<i>Peya</i> , <i>Vilepi</i> , <i>Akrita</i> <i>Yusha</i> , <i>Krita Yusha</i>	According to <i>Agni</i> <i>Bala</i>	Lunch dinner
<i>Samshamana</i> medicine (palliative herbal medicine)	30	<i>Darvyadi Kwatha</i>	80 mL prepared <i>Kwatha</i> twice a days	Before food

Assessment criteria

Objective criteria includes HBA1c, FBS and postprandial blood sugar (PPBS) and subjective criteria includes sign and symptoms of *Prameha*, *Agnibala* (strength of digestion and metabolism), *Dehabala* (physical strength) and *Satvabala* (mental strength)^[19] and quality of life by SF36 score details mentioned in table [Tables 2 and 3].

Outcome

A total of 20 patients of prediabetes were registered, of which 19 patients have completed the course with follow-up and one patient discontinued the treatment due to the emergency condition occurred in home. The observation of the study shows that majority of the patients were belonging to age group of 40–49 years. *Agni* (digestive power) wise distribution shows that maximum patients were *Vishmagni* (disturbed digestion) and *Mandagni* (low or lack of digestive fire and metabolism).^[6] Majority of patients were *Pitta-kapha* and *Vata-Kapha Prakriti* (constitution).^[20]

Primary end point result showed statistically highly significant in HBA1c (MEAN + standard deviation [SD] BT 6.25 + 0.21 and AT 5.63 + 0.36) and secondary end point results showed

also highly significant improvement in FBS (MEAN + SD BT 120.05 + 10.4 and AT 93.31 + 6.9), PPBS (MEAN + SD BT 165.26 + 16.1 and AT 112.84 + 10.9), *Agnibala* (strength of digestion and metabolism), *Dehabala* (physical strength) and *Satvabala* (mental strength) and overall improvement in quality of life (SF-36 Score) [Tables 4 and 5]. Assessment was done for HBA1c on 120th day and other parameters on 46th, 76th, 107th, and 120th day.

Results

All the objective parameters (BT [day 0] mean score 6.25 and AT [day 120] 5.63 [$P < 0.001$]), FBS (BT [day 0] mean score 120.05 and AT [day 120] 93.31 [$P < 0.001$]) and PPBS (BT [day 0] mean score 165.26 and AT [day 120] 112.84 [$P < 0.001$]) have shown statistically highly

Table 3: Assessment criteria of *Agnibala* (~strength of digestion and metabolism), *Dehabala* (physical strength) and *Satvabala* (mental strength)

Assessment parameters

Ruchi (Agnibala)

- Equally willing towards all the *Bhojya Padartha* - 0
- Willing towards some specific *Aahara/Rasavishesha* - 1
- Willing toward only one among *Katu/Amla/Madhura* food stuffs - 2
- Willing towards only most liking foods not to the other - 3
- Unwilling for food but could take the meal - 4
- Totally unwilling for meal - 5

Vaata Mutra PurishaRetasamMukti (Agnibala)

- Occurs easily in normal routine times - 0
- Difficulty in defecation but *Mala Pravritti* daily with discomfort in abdomen - 1
- Can't pass stool daily and feeling heaviness in abdomen - 2
- Passes stool after 3-4 days with *Grathita, Sakasta Mala Pravritti* - 3
- Passes stool after 3-4 days with *Grathita, Sakasta Mala Pravritti* and having gaseous distention with *Udgara Pravritti* - 4

Balavridhhi (Dehabala)

- No weakness - 0
- Slight weakness - 1
- Feeling of weakness but ability to work unaffected - 2
- Ability to work affected - 3
- Can't do any type of work - 4

NidraLabhoYathakalam (Satvabala)

- Sound sleep - 0
- Sleep gets disturbed in the early morning - 1
- Sleeps with disturbed interval and remains unsatisfied with sleep - 2
- Disturbed sleep in night tries to compensate in day - 3
- No sleep in night - 4
- Sleep neither at night nor at night hours - 5

Sukhena - Cha - Pratibodhanam (Satvabala)

- Total relief and feeling of wellbeing at physical and mental level - 0
- Discomfort at mental level - 1
- Discomfort at physical level - 2
- Discomfort at both mental and physical level - 3
- Not feeling well still can pursue work or study - 4
- Not feeling well and not interested in any activity at all (*Avarasatva*) - 5

Table 2: Assessment criteria of sign and symptoms of *Prameha*

Assessment parameters

Prabhutamutrata (polyuria)

- Normal frequency of urine 3-5 times - 0
- Excessive frequency of urine 6-9 times - 1
- Excessive frequency of urine 10-12 times - 2
- Excessive frequency of urine >12 times - 3

Avilmutrata (turbid urine)

- Clear urine - 0
- Slight cloudy or smoky (slight turbidity) - 1
- Turbidity clearly present but news print can be read - 2
- News print cannot be read (more turbid) - 3

Hasatapadatala Daha (burning sensation in palm and feet)

- No burning sensation in hands and feet - 0
- Mild burning sensation in hands and feet - 1
- Moderate burning sensation in hands and feet - 2
- Severe burning sensation in hands and feet - 3

Atipipasa (polydipsia)

- Normal thirst - 0
- Upto 2 L of excess intake of fluids - 1
- Upto 2-3 L of excess intake of fluids - 2
- More than 3 L of excess intake of fluids - 3

Atikshudha (polyphagia)

- No drying of the palate or throat frequently - 0
- Mild dryness of throat and palate frequently - 1
- Moderate dryness of throat and palate frequently - 2
- Very frequently drying up of the throat and palate - 3

Sandhi Shoola (arthritis)

- No pain - 0
- Mild pain - 1
- Moderate pain without swelling - 2
- Severe pain with swelling and difficulty in movement - 3

significant results. Improvement in *Agnibala* (~strength of digestion and metabolism), *Dehabala* (physical strength), and *Satvabala* (mental strength) and quality of life (SF-36 score) were also statistically highly significant [Tables 4-6].

Discussion

Results on all the parameters, were significant particularly HBA1c (<0.001), FBS (<0.001) PPBS (<0.001), *Agnibala* (<0.001), *Dehabala* (<0.001), *Satvabala* (<0.001), and quality of life (SF-36 Score) parameters were shown statistically highly significant results. Prediabetes occur due to change in food habits, irregular sleep pattern, and mental stress or anxiety leads to unbalancing of biological system of the body or in other word in disturbed threshold of the digestion capacity in the intestine and further leads to imbalance in functional

capacity of other system of the body, and gradually imbalance in anatomical structure of the body as well. Metabolic disorder is nothing but imbalance threshold of digestion capacity of the intestine and prediabetes is also one among the metabolic disorders. Pathogenesis of prediabetes starts with *Mandagni* in general and slow *Medodhatvagni* (metabolism of fatty acids) in particular due to which not able to convert glucose into glycogen; hence, blood sugar levels increase in the blood. Apart from this research shown main causative factor is disturbed sleep pattern in reference to biological clock of the patients of prediabetes. In prediabetes patients, *Mandagni* may occur on three, two or one levels such as *Jathragni* (digestive fire), *Dhatvagni* (metabolic function), and *Bhutagni* (neurotransmitters and receptors).^[6]

Vamana Karma is considered as the best treatment for the elimination of *Kapha Dosha* and related body constituents it also

Table 4: Effect of intervention on objective parameters

Parameters	Mean±SD		Percentage decline in mean	t-test	Degrees of freedom	P
	BT (day 0)	AT (120 th days)				
HBA1c	6.25±0.21	5.63±0.36	9.9	7.2	18	<0.001
FBS	120.05±10.4	93.31±6.9	22.2	9.5	18	<0.001
PPBS	165.26±19.1	112.84±10.9	31.7	11.9	18	<0.001

HBA1c: Hemoglobin A1c, FBS: Fasting blood sugar, PPBS: Postprandial blood sugar, SD: Standard deviation, BT=before treatment, AT=after treatment

Table 5: Effect of intervention on subjective parameters

Parameters	Mean±SD		Percentage decline in mean	t-test	Degrees of freedom	P
	BT (day 0)	AT (120 th days)				
<i>Prabhutamurata</i> (polyuria)	0.526±0.904	0.00±0.00	100	2.6	18	<0.05
<i>Avilmurata</i> (turbid urine)	0.21±0.419	0.00±0.00	100	2.2	18	<0.05
<i>Atipipasa</i> (polydipsia)	0.42±0.692	0.00±0.00	100	2.7	18	<0.05
<i>Atikshudha</i> (polyphagia)	0.26±0.562	0.00±0.00	100	2.1	18	0.056
<i>Hastapadatala Daha</i> (burning sensation in palm and feet)	0.37±0.684	0.00±0.00	100	2.4	18	<0.05
<i>Sandhishoola</i> (arthritis)	1.32±1.003	0.32±0.749	75.8	4.9	18	<0.001
<i>Ruchi</i> (<i>Agnibala</i>)	1.26±0.991	0.26±0.452	75.8	3.9	18	<0.001
<i>Vaata Mutra PurishaRetasamMukti</i> (<i>Agnibala</i>)	0.53±0.697	0.11±0.315	79.3	3.1	18	<0.01
<i>Dehabala</i>	1.00±0.745	0.16±0.375	84	6.1	18	<0.001
<i>NidraLabhoYathakalam</i> (<i>Satvabala</i>)	1.47±1.219	0.21±0.419	85.8	5.1	18	<0.001
<i>Sukhena - Cha - Pratibodhanam</i> (<i>Satvabala</i>)	1.11±0.809	0.26±0.452	76.6	5.4	18	<0.001

SD: Standard deviation, BT=before treatment, AT=after treatment

Table 6: Effect of intervention on SF-36 score

Parameters	Mean±SD		Percentage decline in mean	t-test	Degrees of freedom	P
	BT (day 0)	AT (120 th days)				
Physical functioning	50.79±14.55	90.53±10.91	-73.9	-10.9	18	<0.001
Role limitation due to physical health	42.11±18.73	81.58±16.33	-93.7	-8.9	18	<0.001
Role limitation due to emotional problem	42.09±15.11	85.97±16.89	-104.2	-9.9	18	<0.001
Energy/fatigue	54.74±13.69	89.21±12.16	-62.9	-8.8	18	<0.001
Emotional well-being	60.63±8.77	87.16±8.06	-43.8	-12.7	18	<0.001
Social functioning	62.50±13.17	77.63±9.84	-24.2	-5.8	18	<0.001
Pain	60.13±13.32	84.07±12.08	-39.8	-8.7	18	<0.001
General health	51.58±8.82	87.11±12.72	-68.9	-13.9	18	<0.001

SD: Standard deviation, SFshort form survey , BT=before treatment, AT=after treatment

reduces, *Kleda* (excessive *Dravadhathu*), *Abaddhamedha* (increased lipids) which are the major culprits in prediabetes. *Lagenaria siceraria* Linn (bottle gourd [*Ikshvaku*]) was used for *Vamana karma*. It has been indicated in diabetes, hypertension, *Kasa* (asthma), *Shwasa* (chronic obstructive pulmonary disease), *Jwara* (fever), *Gulma* (specific pain in abdomen), *Udara Roga* (ascites), *Granthiganda* (benign tumors and cysts), *Pandu* (anemia and cardiac diseases), *Kushtha* (psoriasis), *Shleepada* (filariasis) and *Visha* (poisoning).^[21] It acts due to hot (*Ushna*), intense (*Teekshna*), subtle (*Sukshma*), pervasiveness (*Vyavayi*) and a substance which first gets dispersed throughout the body and then undergoes transformation (*Vikashi*) property and study shows vomiting (*Urdhvabhagaprabhavata*) effect due to presence of cucurbitacins and its pharmacodynamics action.^[22] *Darvyadi Kwatha* has shown anti-diabetic action it acts on gastrointestinal tract which increases the *Agni* due to ingredient like *Nagarmotha* which has easily digestible (*Laghu*), dry (*Ruksha Guna*) and bitter taste (*Tikta Rasa*), cleansing of GIT due to ingredients like *Haritaki*, *Bibhitaki* and *Amalki* which has laxative and reduces *Kleda* of the body due to ingredients of *Triphala*, *Devdaru*, *Daruharidra* and *Nagarmotha* which has *Ruksha*, *Laghu Guna* action and *Kashaya*, *Tikta Rasa* property.^[23]

Conclusion

Prediabetes commonly affects the middle-aged people living a sedentary life. Positive family history plays a major role in its development. In the early course of disease, *Samshodhana* (bio purification) must be the choice of treatment as, at this stage patient has dominance of *Kapha-Pitta Dosha*. Statistically highly significant results were found, the percent decline in mean of HBA1c (9.9), FBS (22.2) PPBS (31.7), *Agnibala* (*Ruchi* [75.8] and *Vaata Mutra Purisha Retasam Mukti* [79.3]), *Dehabala* (84) and *Satvabala* (*Nidra Labho Yathakalam* [85.8] and *Sukhena-Cha – Pratibodhanam* [76.6]). This study suggests that *Vamana Karma* followed by the oral use of *Darvyadi Kwatha* in the dose of 80 ml in the morning and evening before food can effectively treat prediabetes and prevent landing in diabetes mellitus. No adverse effects were observed during the complete research work.

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Conflicts of interest

There are no conflicts of interest.

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