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# Effect of a medicated yavagu and lifestyle modification in prediabetes: A comparative clinical trial

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## Abstract

Prediabetes is a state of intermediate hyperglycaemia. It remains a high-risk state for developing diabetes mellitus which resembles the concept of *Prameha* in Ayurveda. Prediabetes may be correlated with *Prameha purvarupa,* and they arrive as an opportunity to act early. In Ayurveda, the goal of Prediabetic management is to normalise the blood sugar level by giving attention to three aspects - *Aushadha* (Medicine), *Ahara* (Diet) and *Vyayama* (Exercise). This study is to assess the effect of a Medicated *yavagu* and Lifestyle modification in Prediabetes. This Medicated *yavagu* is mentioned in the Kerala's traditional therapeutic treatise Yogamrutam, *Prameha chikitsa.* It is prepared with *Raktasali (Oryza sativa)* and *Mudga (Vigna radiata)* in *kashaya* of 8 herbal ingredients-*Paaranthi* root *(Ixora coccinea)*, *Khadira sara (Acacia catechu)*, *Bhadra* root *(Aerva lanata)*, *Saalaparni* root *(Pseudarthria viscida), Dusparsa* root *(Tragia involucrata)*, *Vasukah* root *(Spermacoce hispida)*, *Daaruharidra* stem *(Coscinium fenestratum)* and *Ghotika* root *(Portulaca oleracea)*. A Pre-post Interventional study was done in 60 participants with 30 each randomly allocated to Intervention group (Group I) and Comparison group (Group II). In Group I, Medicated *yavagu* was administered along with Lifestyle modification which includes dietary restriction and exercise. In Group II, Lifestyle modification alone was advised. The study period was 30 days. FBS and PPBS levels were analyzed on $0^{th}$, $15^{th}$ and $31^{st}$ day. The study was analyzed statistically using paired t-test, student's t-test and repeated measures ANOVA. After intervention, both Group I and II elicited statistically highly significant reduction in FBS and PPBS values ($p<0.001$). When comparing both groups, the effect was statistically highly significant ($p<0.001$) in reducing FBS and PPBS levels. The results indicates that Medicated *yavagu* along with Lifestyle modification is more effective than Lifestyle modification alone in Prediabetes.

**Keywords:** Prediabetes; *Prameha*; *Prameha purvarupa*; Medicated *yavagu*; Lifestyle modification

## 1. Introduction

Increase in prevalence of diabetes mellitus has reached alarming proportions and is putting burden on healthcare systems around the world. Prediabetes, also called as intermediate hyperglycaemia, is a stage before manifestation of full-blown diabetes mellitus [1]. Concept of *Prameha* in Ayurveda have resemblance with the latest knowledge on diabetes mellitus as known in conventional medical sciences. Prediabetes may be correlated with *Prameha purvarupa.* Both Prediabetes and *Prameha purvarupa* arrives as an opportunity to act early through their timely observation, which eventually help to bring effective lifestyle changes, so that its progress to *Prameha* or diabetes may be arrested.

Condition in which an individual is having blood glucose levels higher than normal but not high enough to be classified as diabetes is called Prediabetes and they have an increased risk of developing type 2 diabetes [2]. Various organizations have defined Prediabetes with criteria that are not uniform. Definition of Prediabetes according to the World Health Organization is - a state of intermediate hyperglycemia using two specific parameters, impaired fasting glucose (IFG)

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defined as fasting plasma glucose (FPG) of 110 to 125 mg/dL (6.1 – 6.9 mmol/L) and impaired glucose tolerance (IGT) defined as 2-h plasma glucose of 140 – 200 mg/dL (7.8 – 11.0 mmol/L) after ingestion of 75g of oral glucose load or a combination of the two based on a 2-h oral glucose tolerance test (OGTT). The American Diabetes Association (ADA) has the same cut-off value for IGT (140-200 mg/dL) but has a lower cut-off value for IFG (100 -125 mg/dL) and an additional hemoglobin A1c (HbA1c) based criteria level of 5.7% to 6.4% for definition of Prediabetes [3]. About 471 million people are having Prediabetes around the world and India stands 2nd in the number of Prediabetes patients. According to National Urban Diabetes Survey, the estimated prevalence of Prediabetes in India is 14 % [4].

Number of diabetic cases and prevalence of diabetes are steadily increasing over past few decades. About 422 million people worldwide have diabetes, majority belonging to low and middle-income countries and 1.6 million deaths are directly attributed to diabetes each year. The International Diabetes Federation has estimated that there will be 642 million diabetics by 2040 worldwide. In India, the prevalence of diabetes is estimated to be 8.7% [1].

In a country like India, having a sizeable population of diabetic patients, one needs to reiterate the necessity of identifying Prediabetes and plan on Lifestyle modification for all individuals [4]. Various studies conducted on Prediabetic individuals for preventing its progression to diabetes include - metformin, and various other medicines like orlistat, acarbose, pioglitazone. However, adverse reactions of medicines were reported to be the major hurdle in long term sustainability of these interventions. Hence, global interest is increasing towards search for safe and effective remedies for preventing progression from Prediabetes to diabetes, which can be provided by Ayurveda.

The scope of the study is primary level prevention of diabetes using safe and effective remedies described in Ayurveda. Ayurveda is the science of life with the aim of prevention of disease and preservation of health of the individual which can be achieved through the branch named *Swasthavritta*. It emphasises the role of daily regimen (*Dinacharya*), seasonal regimen (*Rtucharya*), diet (*Ahara*), rejuvenation therapy (*Rasayana)* etc. for maintaining good health in general.

Diabetes mellitus and Prediabetes may be correlated with the concepts of *Prameha* and *Prameha purvarupa* in Ayurvedic Classics. Prediabetes and *Prameha purvarupa,* are the signs of the upcoming risk for development of diabetes, which give an opportunity for early diagnosis and management. Like conventional medicine, in Ayurveda, the goal of Prediabetic management would be to normalise the blood sugar level by giving comprehensive attention to three aspects - *aushadha* (medicine), *ahara* (diet) and *vyayama* (exercise). In the present study, combination of the above strategies is adopted. Aetiology of diabetes is multifactorial and multi targeted herbal drugs would be comparatively safer than modern drugs to be used in management of Prediabetes and prevention of its progress to diabetes [1].

Reduction in blood sugar, decrease in insulin resistance, and improvement in beta cell activity is exhibited by various herbs mentioned in Ayurveda literature [1]. The Medicated *yavagu* in the study is taken from *Prameha chikitsa* chapter of the Text Yogamrutam [5]. The Medicated *yavagu* is prepared with *Raktasaali (Oryza sativa Linn.)* and *Mudga (Vigna radiata Linn.)* in *kashaya* of 8 herbal ingredients - *Paaranthi (Ixora coccinea Linn.), Bhadra (Aerva lanata Linn.), Saalaparni (Pseudarthria viscida Linn.), Ghotika (Portulaca oleracea Linn.), Vasukah (Spermacoce hispida Linn.), Khadira (Acacia catechu Linn. f), Dusparsa (Tragia involucrata Linn.)* and *Daaruharidra (Coscinium fenestratum Gaerten).*

Along with the Medicated *yavagu*, Lifestyle modification including diet regimen and exercise, is given. Eating habits, decreased physical activity, smoking, increasing weight etc. are major factors leading to type 2 diabetes mellitus. Long term data on Lifestyle modification gives evidence for the prevention of progression of Prediabetes to diabetes mellitus. Thus, a combination of a medicated diet and lifestyle modification which incorporates all the three aspects of *Prameha* management can be considered as an ideal primary level therapeutic option for diabetes prevention. Therefore, this study is aimed to assess the effect of a Medicated *yavagu* and Lifestyle modification in Prediabetes.

## 2. Material and methods

### 2.1. Packing, Dispensing and Method of preparation of *Yavagu*

The drugs mentioned in Table 1, of superior quality were properly identified and purchased from approved sources. These drugs were washed perfectly in running water to remove mud and other foreign materials. Then all were dried in shade and the drugs for *kashaya* preparation were made into coarse powder.

48 gm of *kashaya choorna* consisting of 8 herbal ingredients each in equal quantity (6 gm) and 36 gm of *raktasali* (rice) and 28 gm of *mudga* (green gram) were packed in separate packets and sealed. In the beginning, the participants were given a set of packets containing 15 packets each of *kashaya choorna*, *raktasali* and *mudga* - for 15 days. The method of

preparation of *yavagu* was explained individually and it was also printed in regional language and enclosed in the set of packets. After 15 days, the participants were asked to collect the next set of 15 packets. They were instructed to prepare *yavagu* with the medicine and take it as dinner regularly for a period of 30 days.

**Table 1** Ingredients of Medicated *Yavagu*

| Sl. No. | Ingredients | Botanical Name | English Name |
|---|---|---|---|
| 1 | *Raktasali* | *Oryza sativa Linn.* | Rice |
| 2 | *Mudga* | *Vigna radiata Linn.* | Green gram |
| 3 | *Paaranthi* root | *Ixora coccinea Linn.* | Ixora |
| 4 | *Bhadra* root | *Aerva lanata Linn.* | Mountain Knotgrass |
| 5 | *Saalaparni* root | *Pseudarthria viscida Linn.* | Viscid pseudarthria |
| 6 | *Ghotika* or *brhat loni* root | *Portulaca oleracea Linn.* | Common purslane |
| 7 | *Vasukah* root | *Spermacoce hispida Linn.* | Shaggy button weed |
| 8 | *Khadira* heartwood | *Acacia catechu Linn.f* | Cutch tree |
| 9 | *Dusparsa* root | *Tragia involucrata Linn.* | Indian stinging nettle |
| 10 | *Daaruharidra* stem | *Coscinium fenestratum Gaerten.* | Tree turmeric |

For preparing *kashaya,* 48 gm of the *kashaya choorna* is added with 768 ml (16 times) water and boiled and reduced to 384 ml (half) and filtered to prepare *yavagu*. The *raktasali* and *mudga* were taken 64 gm (1/6 parts of *kashaya*). The method of preparation of Medicated *yavagu (kwathasadhya yavagu)* used in the study was adopted from Sharangadhara Samhitha: Madhyama khanda [6]. *Raktasali* (rice) and *mudga* (green gram) were taken 36 gm and 28 gm respectively based on the approximate ratio of carbohydrate and protein requirement in the diet of a diabetic person [7] and is cooked well in the already prepared *kashaya* to prepare gruel (*yavagu)*. The participants were instructed to take this traditional gruel as dinner at 8.00 pm regularly for a period of 30 days.

*2.1.1. Study setting*

Government Ayurveda Panchakarma Hospital, Poojappura, Thiruvananthapuram, Kerala, India

*2.1.2. Data Collection*

Data was gathered from each sample using a case proforma and laboratory investigations of blood (FBS, PPBS, HbA1c) was done before ($0^{th}$ day) the administration of intervention and FBS and PPBS were done on $15^{th}$ day and after ($31^{st}$ day) the intervention.

### 2.2. Sampling

**Study Population**- Participants of either sex aged between 30–60 years, having FBS value–100-125 mg/dL.

*2.2.1. Inclusion Criteria*

- Participants of both sexes
- Participants in the age group of 30-60 years
- Having FBS value between 100-125 mg/dL
- Having HbA1c value between 5.7-6.4 %

*2.2.2. Exclusion Criteria*

- Diabetes mellitus type 1
- PPBS value above 199 mg/dL
- Gestational diabetes
- Participants under hypoglycemic drugs
- Chronic systemic diseases

- Endocrine disorders and untreated thyroid problems

### 2.3. Sampling Procedure

From accessible population who satisfies the inclusion and exclusion criteria, a sample of 60 participants were selected and randomly assigned to 2 groups with 30 each in Intervention group (Group I) and Comparison group (Group II).

### 2.4. Data Collection

Data was gathered from each sample using-A case proforma and laboratory investigations of blood (FBS, PPBS, HbA1c) was done before ($0^{th}$ day) the administration of intervention and FBS and PPBS were done on $15^{th}$ day and after ($31^{st}$ day) the intervention.

### 2.5. Study Tools

- Case proforma
- FBS and PPBS values

### 2.6. Statistical Analysis

Quantitative variables were expressed as mean, SD, minimum, maximum, median and inter quartile range. Qualitative variables were expressed as frequency distribution. Comparison of quantitative variables between two group were analysed by unpaired t-test or student's t-test or Mann-Whitney U test according to the nature of the data. Pre-test post comparison of quantitative variables was analysed by paired t-test or Wilcoxon signed rank test according to the nature of the data. Comparison of qualitative variables between two group were analysed by Chi square test. A p value $< 0.05$ is considered as statistically significant. For data analysis, SPSS version 16.0 was used. Student's t-test was applied for comparing the effect due to the intervention in both the groups. Paired t-test was applied to assess the change within the groups separately before and after the study. Repeated measures ANOVA was done to confirm that the changes in FBS and PPBS levels significantly varies over the two groups.

### 2.7. Procedure

#### *2.7.1. Selection of participants*

Participants with FBS value between 100-125mg/dL, who visited the OPD of Dept. of Swasthavritta, Govt. Ayurveda Panchakarma Hospital, Poojappura were screened initially. As per the inclusion and exclusion criteria, 60 participants were selected. The selected participants were randomly allocated into two groups with 30 each in Intervention group (Group I) and Comparison group (Group II). They were examined at clinical and investigative level by using the case proforma. The laboratory parameters like FBS, PPBS, and HbA1c were analyzed before the study period ($0^{th}$ day) and FBS and PPBS values were analyzed in the middle ($15^{th}$ day) and after the study period ($31^{st}$ day).

#### *2.7.2. General directions before the Intervention*

Selected participants of both groups were made aware of the importance of following controlled diet and exercise in Prediabetes. They were advised to take fibre rich, low calorie food items in small quantities in frequent intervals by including more vegetables such as green leafy vegetables, salads etc. Junk foods like bakery items, refined wheat flour preparations, fried items, pickles, excess sugar, ice creams, chocolate shakes, soft drinks, fast foods etc. were completely avoided during the study period. The intervention and comparison groups were advised to take 30 minutes brisk walking daily 8am in the morning. The Intervention group, was instructed to take Medicated *yavagu* as dinner.

#### *2.7.3. Intervention group (GROUP I)*

The Intervention group was given a set of packets of raw drugs, which contains 15 separately packed- 48 gm of coarsely powdered *kashaya choorna* of 8 herbal drugs (6gm each), 28 gm *mudga* (green gram) and 36gm *raktasali* (rice). After 15 days the next set of 15 packets will be dispensed to avoid unwanted medicine loss due to dropouts and to ensure that the participants has consumed the *yavagu* without fail as dinner preferably at 8.00pm for a period of 30 days regularly. Along with Medicated *yavagu*, Lifestyle modification which include dietary restriction and 30 minutes brisk walk were advised.

#### *2.7.4. Comparison group (GROUP II)*

The Comparison group were given same advises regarding Lifestyle modification which include dietary restriction and 30 minutes brisk walk which are given as diet and exercise charts, and they were under observation during the study

period. On ethical consideration, the participants of the Comparison group were given the drugs to prepare Medicated *yavagu*, after the completion of the study.

### 2.8. Outcome variable

Changes in Fasting Blood Sugar and Postprandial Blood Sugar level

## 3. Results and discussion

The response to treatment was assessed by evaluating the criteria - Fasting Blood Sugar (FBS) and Postprandial Blood Sugar (PPBS) levels. The variables were assessed at three points of time, i.e., Before Treatment (BT), Middle of the Treatment (MT) and After Treatment (AT). Interpretations based on variables are given below. Paired t-test was done to analyse the results within the group, student's t-test (independent or unpaired t-test) was to analyse the results between the groups, repeated measures ANOVA was done to confirm that the change in blood level significantly varies over the two groups. The obtained results were interpreted in the statistical terms as: Highly Significant (HS): $p<0.001$, Significant (S): $p<0.05$, Not Significant (NS): $p>0.05$.

### 3.1. Effect of treatment on Fasting Blood Sugar (FBS)

On analysis, Chart 1 and Table 2 shows the fasting blood sugar values Before Treatment (BT), Middle of the Treatment (MT) and After Treatment (AT). It is observed that there is considerable reduction in fasting blood sugar value of participants in Intervention group (Group I) and Comparison group (Group II).

**Table 2** Effect of treatment on Fasting blood sugar

| GROUPS | Stages of Intervention | N | FBS (mg/dL) | |
|---|---|---|---|---|
| | | | Mean | SD |
| Group I | BT | 30 | 119.6 | 4.3 |
| | MT | 30 | 111.3 | 5.7 |
| | AT | 30 | 101.3 | 9.6 |
| Group II | BT | 30 | 117.2 | 5.7 |
| | MT | 30 | 114.5 | 6.2 |
| | AT | 30 | 112.0 | 6.5 |

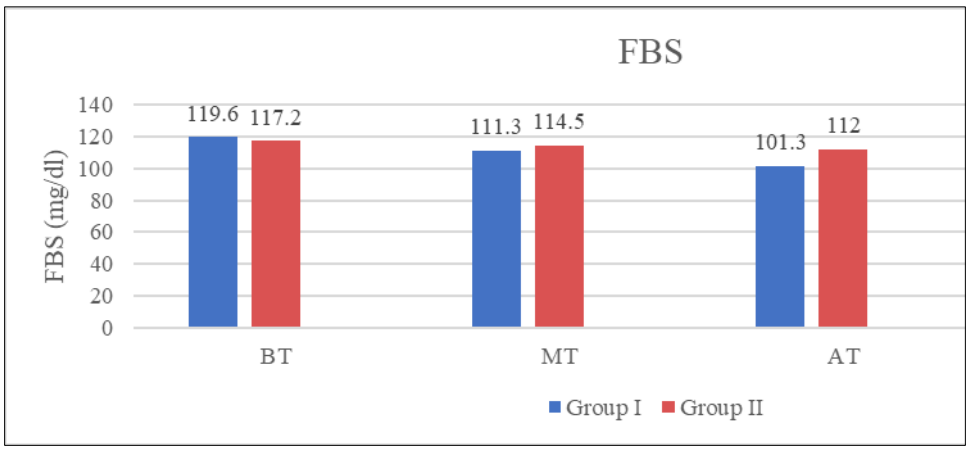


**Figure 1** Effect of treatment on FBS level

Paired t-test was separately conducted in Group I and Group II to compare the statistical significance of change in FBS level between the different stages of intervention.

**Table 3** Paired Comparison (Different stages of Intervention)

| GROUPS | | N | FBS (mg/dL) | | Paired comparison | Paired Differences | | 95% CI of the Difference | | Paired t-test | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Mean | SD | | Mean | SD | L | U | t | p |
| Group I | BT | 30 | 119.6 | 4.3 | BT vs MT | 8.27 | 3.40 | 7.00 | 9.54 | 13.305 | 0.000 |
| | MT | 30 | 111.3 | 5.7 | MT Vs AT | 10.03 | 6.53 | 7.59 | 12.47 | 8.414 | 0.000 |
| | AT | 30 | 101.3 | 9.6 | BT vs AT | 18.30 | 8.05 | 15.29 | 21.31 | 12.448 | 0.000 |
| Group II | BT | 30 | 117.2 | 5.7 | BT vs MT | 2.67 | 1.81 | 1.99 | 3.34 | 8.084 | 0.000 |
| | MT | 30 | 114.5 | 6.2 | MT Vs AT | 2.50 | 1.61 | 1.90 | 3.10 | 8.486 | 0.000 |
| | AT | 30 | 112 | 6.5 | BT vs AT | 5.17 | 2.38 | 4.28 | 6.06 | 11.894 | 0.000 |

The table 3 reveals significant reduction in the FBS values on comparison between different stages of intervention in Group I and Group II separately i.e., Before Treatment (BT), Middle of the treatment (MT) and After treatment (AT). FBS value showed reduction in both Group I and Group II when compared between different levels of intervention (BT vs MT, MT vs AT and BT vs AT). The reduction in FBS was statistically highly significant at $p<0.001$ in both groups.

**Table 4** Comparison between effect of treatment on FBS levels of 2 groups

| FBS (mg/dL) | Group I | | Group II | | Student's t test | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | t | p |
| BT | 119.6 | 4.3 | 117.2 | 5.7 | 1.829 | 0.073 |
| MT | 111.3 | 5.7 | 114.5 | 6.2 | 2.079 | 0.042 |
| AT | 101.3 | 9.6 | 112.0 | 6.5 | 5.105 | <0.001 |

Student's t-test (Independent sample t test) was done to compare the average changes in FBS levels at different stages of intervention between both Groups. Mean FBS values of Group I and Group II Before Treatment (BT) was found to be 119.6 and 117.2 mg/dL respectively ($p>0.05$). Comparison between FBS values obtained at Middle of Treatment (MT) of 2 Groups was found to be statistically significant at $p<0.05$. Comparison between FBS values obtained After Treatment (AT) of both Groups was found to be statistically highly significant at $p<0.001$.

**Table 5** Repeated measures ANOVA (FBS level)

| Source | Type III Sum of Squares | df | Mean Square | F | p |
|---|---|---|---|---|---|
| Time factor | 4136.5 | 2.0 | 2068.3 | 190.0 | 0.000 |
| Time vs Category | 1303.0 | 2.0 | 651.5 | 59.9 | 0.000 |
| Error | 1262.5 | 116.0 | 10.9 | | |

The p value in repeated observations reveals that the change in FBS levels in successive observations were statistically significant ($p<0.001$). The p value shown for the interaction was statistically significant i.e., the change in FBS level significantly varies over the 2 groups.

### 3.2. Effect of treatment on Postprandial Blood Sugar (PPBS)

The chart 2 and Table 6 show the postprandial blood sugar values Before Treatment (BT), at the Middle of the Treatment (MT) and After Treatment (AT). It is observed that there is considerable reduction in PPBS value of participants in Intervention group (Group I) and Comparison group (Group II).

**Table 6** Effect of treatment on PPBS level

| GROUPS | Stages of Intervention | N | PPBS (mg/dL) | |
|---|---|---|---|---|
| | | | Mean | SD |
| Group I | BT | 30 | 174.1 | 14.7 |
| | MT | 30 | 159.0 | 15.4 |
| | AT | 30 | 146.4 | 14.5 |
| Group II | BT | 30 | 169.5 | 12.5 |
| | MT | 30 | 165.8 | 13.1 |
| | AT | 30 | 161.9 | 12.6 |

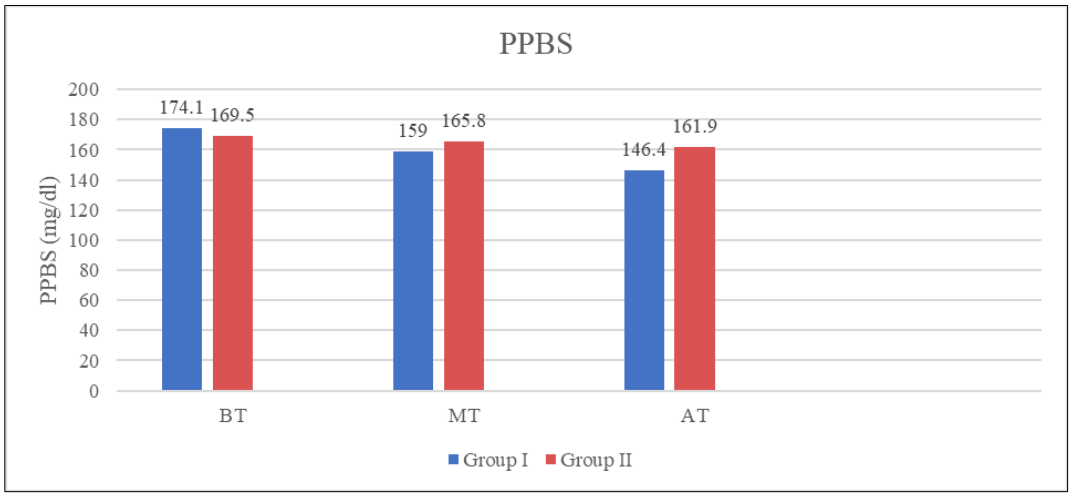


**Figure 2** Effect of treatment on PPBS level

Paired t-test was separately conducted in Group I and Group II to compare the statistical significance of change in PPBS level between the different stages of treatment.

**Table 7** Paired comparison (Different stages of Intervention)

| GROUPS | | N | PPBS (mg/dL) | | Paired comparison | Paired Differences | | 95% CI of the Difference | | Paired t-test | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Mean | SD | | Mean | SD | L | U | t | p |
| Group I | BT | 30 | 174.1 | 14.7 | BT vs MT | 15.13 | 12.48 | 10.47 | 19.79 | 6.644 | 0.000 |
| | MT | 30 | 159.0 | 15.4 | MT vs AT | 12.63 | 7.59 | 9.80 | 15.47 | 9.116 | 0.000 |
| | AT | 30 | 146.4 | 14.5 | BT vs AT | 27.77 | 14.65 | 22.30 | 33.24 | 10.380 | 0.000 |
| Group II | BT | 30 | 169.5 | 12.5 | BT vs MT | 3.77 | 1.70 | 3.13 | 4.40 | 12.168 | 0.000 |
| | MT | 30 | 165.8 | 13.1 | MT vs AT | 3.90 | 2.90 | 2.82 | 4.98 | 7.354 | 0.000 |
| | AT | 30 | 161.9 | 12.6 | BT vs AT | 7.67 | 3.11 | 6.51 | 8.83 | 13.498 | 0.000 |

The Table 7 reveals the reduction in the PPBS values on comparison between different stages of intervention in Group I and Group II separately i.e., Before Treatment (BT), Middle of the treatment (MT) and After treatment (AT). PPBS value

showed reduction in both Group I and Group II when compared between different levels of intervention (BT vs MT, MT vs AT and BT vs AT). The reduction in PPBS was statistically highly significant at p<0.001 in both groups.

**Table 8** Comparison between effect of treatment on PPBS levels of two groups

| PPBS (mg/dL) | Group I | | Group II | | Student's t-test | |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | t | p |
| BT | 174.1 | 14.7 | 169.5 | 12.5 | 1.304 | 0.197 |
| MT | 159.0 | 15.4 | 165.8 | 13.1 | 1.832 | 0.072 |
| AT | 146.4 | 14.5 | 161.9 | 12.6 | 4.412 | <0.001 |

Student's t-test (Independent sample t test) was carried out to compare the average change in PPBS levels at different intervention stages between Group I and Group II. Mean PPBS values of Group I and Group II Before Treatment (BT) was found to be 174.1 and 169.5 mg/dL respectively (p>0.05). Comparison between PPBS values obtained at Middle of Treatment (MT) of 2 Groups was not found statistically significant with p>0.05. Comparison between PPBS values obtained After Treatment (AT) of both Groups was found to be statistically highly significant at p<0.001.

**Table 9** Repeated Measures ANOVA (PPBS Level)

| Source | Type III Sum of Squares | df | Mean Square | F | p |
|---|---|---|---|---|---|
| Time factor | 9430.411 | 2 | 4715.206 | 126.043 | 0.000 |
| Time vs Category | 3047.411 | 2 | 1523.706 | 40.730 | 0.000 |
| Error | 4339.511 | 116 | 37.410 | | |

The p value in repeated observations shows that the change in PPBS levels significantly varies over 2 groups. The p value is statistically significant at p<0.001 i.e., the change in PPBS level significantly varies over the 2 groups.

## 4. Discussion

The response to treatment was assessed by evaluating the change in FBS and PPBS levels. The variables were evaluated at three points of time i.e., Before Treatment (BT), Middle of the Treatment (MT) and After Treatment (AT). An independent sample t-test (student's t-test) was carried out to compare the means of change in blood sugar values between the Intervention and Comparison groups. Paired t-test was done separately in the two groups to compare the statistical significance of change in blood sugar levels between the different stages of intervention. As the blood sugar values are checked at three different time period of intervention, repeated measures ANOVA was used in the study.

### 4.1. Effect on fasting blood sugar level

Statistically highly significant reduction was found in fasting blood glucose level in both groups (p<0.001) when compared with different stages of intervention in both groups. The mean value of FBS in the Intervention group (Group I) before treatment was 119.6mg/dL and after treatment was 101.3mg/dL. The mean FBS value in the Comparison group (Group II) was 117.2mg/dL before treatment and 112mg/dL after treatment. Hence highly significant reduction in FBS value was noted in Intervention group than Comparison group (p<0.001). The result indicates that both Medicated *yavagu* and Lifestyle modification has effect in reducing the FBS levels, while the combination of Medicated *yavagu* and Lifestyle modification is more effective than Lifestyle modification alone.

### 4.2. Effect on Postprandial blood sugar level

Statistically highly significant reduction was found in postprandial blood glucose level in both groups (p<0.001) when compared between different stages of intervention. The mean value of PPBS in the Intervention group (Group I) before treatment was 174.1mg/dL and after treatment was 146.4mg/dL. The mean PPBS value in the Comparison group (Group II) was 169.5mg/dL before treatment and 161.9mg/dL after treatment. Hence highly significant reduction in

PPBS value was noted in Intervention group than Comparison group ($p<0.001$). The result indicates that both Medicated *yavagu* and Lifestyle modification has effect in reducing the PPBS levels, while the combination of Medicated *yavagu* and Lifestyle modification is more effective than Lifestyle modification alone.

### 4.3. Probable Mode of Action

*Prameha* is a *Kapha* predominant condition even though all the three *Doshas* are involved in its manifestation. The *kaphakara aharas* causes *agnimandya* and leads to *ama* condition in the body due to defective metabolism. The continuous usage of unwholesome diet and regimen (*apathya ahara vihara* preferably *snigdha ahara* or high calorie food) vitiates *medo dhatu* and it will cause the obstruction to the development of other *dhatus*. Here, the drugs having the tastes of *kashaya* (astringent)*, katu* (pungent)*, tiktha* (bitter) *and katu vipaka* (pungent taste conversion after digestion)*; laghu ruksha guna* (light and non-unctuousness quality) and *ushna virya* (hot potency) can be used for the treatment of *Prameha*.

*Katu rasa* (pungent taste) possess *gunas* like *laghu* and *ruksha* and it can decrease the *kleda, kapha* and *mutra* in the body. *Kashaya rasa* clears the channels due to *kapha shoshana* property (absorption of *kapha*) and *kledahara* property. *Tiktha rasa* (bitter taste) is predominant of *Akasha* (ether) and *Vayu* (air) *mahabhoota*. *Tiktha rasa* decreases *kapha* and *pitta* and it is opposite to *snigdha guna* and is having *deepana* (carminative), *paachana* (increases digestion), *lekhana* (clears the channels), *raktaprasaadana* (eliminate toxicity from the blood) and *kleda-medahara* (decreases moisture and cholesterol from the body) properties, hence have the ability to permeate the *sushmastrotasas* (minute channels). *Katu vipaka* helps to increase the digestion, thus stimulating the *Jatharagni* and regularizes the *Mandagni* which is the main cause of *Prameha*. *Laghu* and *ruksha guna* also clears the *mala* and *kleda* (toxicity and cholesterol) from *strotas* (channels). As *kapha* and *kleda* are having *sheeta guna* (cold quality) it is advised to take *ushna virya* drugs (hot potency), beneficial for *samprapti bhedana*. The herbals having the above qualities may reach the cellular level and helps to reduce *meda* and *kleda* involved in the *purvarupa* of *Prameha* pathology and thereby reducing the related symptoms.

*Paaranthi (Ixora coccinea Linn.)* has *kashaya, tiktha rasa, laghu guna, katu vipaka* and is *seetha virya* in nature helps in *pitta samana* [8]. Research works done on *Paaranthi* shows that hypoglycaemic and hypolipidemic activity which may be due to enhanced secretion of insulin from pancreatic β-cell and by increased tissue uptake of glucose by enhancement of insulin sensitivity [9]. The active constituents responsible for the hypo-glycaemic activity is not known but it may be attributed to the presence of phytocomponents like alkaloids, flavonoids, saponins, tannins, anthraquinones and reducing sugars [10].

*Bhadra (Aerva lanata Linn.) has tiktha, kashaya rasa*; *katu vipaka; laghu teekshna guna* and is *ushna veerya* in nature. It has *kapha vata samana* property [11]. Research works done on *Bhadra* suggests that the anti-diabetic activity of the plant may be due to its high phenol content, antioxidant activity and free radical scavenging ability [9]. The study – Antidiabetic activity of alkaloids of *Aerva lanata* roots on streptozotocin-nicotinamide induced type-II diabetes in rats, established that partially purified alkaloid basified toluene fraction (PPABTF) of roots of the plant exhibited significant antihyperglycemic activities and showed improvement in regeneration of β-cells of pancreas and so might be of value in diabetes treatment. The study states that this activity may be due to the presence of alkaloids like canthin-6-one derivatives in the root [12].

*Saalaparni (Pseudarthria viscida Linn.)* is having *madhura tiktha rasa; guru, snigdha guna; ushna virya* and *tridosha samaka* property [13]. The study -Antidiabetic activity of *Pseudarthria viscida* aqueous root extract in neonatal streptozotocin-induced noninsulin -dependent diabetes mellitus (NIDDM) rats, established significant increase in serum insulin levels indicating that it may probably activate the surviving β-cells of islets of Langerhans and revert them to normal state i.e., an insulinogenic effect. The administration of the extract decreased the concentration of glycated haemoglobin which may be due to an increase in insulin secretion. The study says that this activity of the plant may be attributed to the presence of tannins, leucopelargonidin derivatives [14].

*Ghotika (Portulaca oleracea Linn.)* has *kashaya, katu, amla rasa, guru, ruksha guna* and *vata-kapha samaka* property [15]. In the study–Anti-Diabetic Effect of *Portulaca oleracea L.* Polysaccharide and its Mechanism in Diabetic Rats, the antidiabetic activity of polysaccharide extract was studied. The results indicate that the oral administration of CPOP (crude *Portulaca oleracea L.* polysaccharide) could significantly improve the glucose tolerance in diabetic rats and significantly reduce the fasting blood glucose level and this anti-diabetic effect may be associated with its antioxidant and anti-inflammatory effects [16].

*Vasukah (Spermacoce hispida Linn.)* has *katu tiktha rasa, sheeta virya* and *kapha pittahara* property [17]. *Spermacoce hispida* was investigated and reported to have hypoglycaemic activity upon subcutaneous administration in animal

model of diabetes. The oral administration of *Spermacoce hispida* in alloxan induced diabetic rats showed significant hypoglycaemic effect [18].

*Khadira (Acacia catechu Linn.)* is having *tiktha, kashaya rasa, laghu, ruksha guna, sheeta virya, katu vipaka* and *kapha pitta samaka* property [19]. *Acacia catechu* is found to increase the level of beta cells, thus encouraging them to secrete more insulin which is helpful for type 2 diabetes mellitus. It also helps to lose body weight and its adrenergic amine content stimulates beta- receptors to break down the lipids in the body. This, in turn, enhances the rate of metabolism [20].

*Dusparsa (Tragia involucrata Linn.)* is having *katu, tiktha rasa, ushna virya, katu vipaka* and *vata-pittaghna* property [21]. In the study - In vitro antidiabetic activity of *Tragia involucrata Linn.* Leaf extracts, the results showed that the plant extract have potent α-amylase enzyme inhibitory activity. Steroids and terpenoids present in the plant have been reported to possess anti-diabetic activity individually. Therefore, their combined presence in aqueous, ethyl acetate and chloroform extracts might contribute to the evident antidiabetic activity of the extracts [22].

*Daaruharidra (Coscinium fenestratum Gaertn.)* is having *tiktha, kashaya rasa; laghu, ruksha guna, ushna virya, katu vipaka* and *kapha pitta hara* property [23]. In the study – Antidiabetic activity of alcoholic stem extract of *Coscinium fenestratum* in streptozotocin-nicotinamide induce type 2 diabetic rats, significant reduction in blood glucose levels were observed. The study says that the antidiabetic activity of the stem extract may be attributed to its chemical constituent berberine and the hypo-glycaemic effect might be probably due to an extra pancreatic mechanism. In vitro studies have shown that berberine is able to exert an insulin independent glucose lowering effect in hepatocytes similar to metformin [24].

*Raktasali (Oryza sativa Linn.)* is having *madhura rasa, guru, snigdha guna, sheetha virya* and *pittagna, vata-kapha vardhana* property [25]. The bran layer of pigmented rice contains anthocyanins and proanthocyanidins. In the study- Anti-diabetic potential of purple and red rice *(Oryza sativa L.)* bran extracts, the phenolic, flavonoid, anthocyanin, and proanthocyanidin content was found. Bran extract from each type was evaluated for inhibitory effects on α-amylase and α-glucosidase activity, two key glucosidases required for starch digestion in humans. Both purple and red bran extracts inhibited α-glucosidase activity. The red rice bran extracts exhibited glucose uptake activity and inhibited α-amylase activity [26].

*Mudga (Vigna radiata Linn.)* is having *kashaya madhura rasa, laghu ruksha guna, sheeta virya* and is *pitta kapha samana* in action [27]. The study- Anti-diabetic activity of aqueous extract from *Vigna radiata* in streptozotocin induced diabetic mice, indicates that the probable mechanism of the aqueous extract of *Vigna radiata* might be by increasing insulin secretion from the pancreatic β-cells by closing the adenosine triphosphate sensitive potassium channels. Previous phytochemical screening of the plant extract has also showed that the extracts from *Vigna radiata* contain free phenolic acids, bound phenolic acids and anthocyanin. These constituents were reported to be responsible for the antidiabetic activity of this plant [28].

The probable mode of action of diet control may be explained on the basis of the study – Dietary and nutritional approaches for prevention and management of type 2 diabetes, which says that, the influence of diet on glycemia, and glucose-insulin homeostasis is directly relevant to glycaemic control in diabetes. The effect of food and nutrients may also be relevant to the pathogenesis of diabetes. Therefore, diet quality and quantity over a longer time period are relevant to the prevention and management of diabetes and its complications through a wide range of metabolic and physiological processes [29].

The study – Daily Physical Activity and Type 2 Diabetes, provides evidence of the efficacy of walking in preventing progression of Prediabetes to type 2 diabetes mellitus and reducing the risk of mortality and cardiovascular events. Also, various previous studies have suggested that brisk walking for at least 30 minutes per day is needed to reduce the risk of developing type 2 diabetes. Walking improves insulin sensitivity, glycaemic control and incidence of obesity [30].

## 5. Conclusion

The aim of the study was to find out the effect of a Medicated *yavagu* and Lifestyle modification in Prediabetes. Prediabetes is a condition, with a reversible pathology and are the signs of the upcoming disease which arrive as an opportunity to act early through their timely identification. Adoption of primary preventive measures at this stage can prevent the progression of Prediabetes to diabetes. Unhealthy eating habits, sedentary lifestyle and lack of physical activity are the main causes of Prediabetes. Majority of the participants with Prediabetes had a family history of diabetes mellitus and here comes the importance of primary preventive measures. The intervention, Medicated *yavagu* along

with Lifestyle modification have achieved the objective of the study by reducing the fasting and postprandial blood sugar levels in the Intervention group compared to Comparison group with Lifestyle modification alone. Therefore, it is concluded that there is significant difference between the effect of Medicated *yavagu* along with Lifestyle modification and Lifestyle modification alone in Prediabetes.

## Compliance with ethical standards

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### *Disclosure of Conflict of interest*

No conflict of interest to be disclosed.

### *Statement of ethical approval*

Approval from the Institutional Ethical Committee (Ref. No. AVC IEC 413/2019) was also obtained prior to the study.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

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