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Clinical efficacy of haridra in prameha purvaroop w.s.r. to prediabetes

Research Article

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Abstract

Diabetes is a non-communicable disease which is attaining increasing importance among the adult population in both developed and developing countries. Pre-diabetes is a precursor condition for type 2 Diabetes mellitus. Although in many cases it is reversible, Pre-diabetes frequently remains undiagnosed and therefore risk of developing type 2 Diabetes Mellitus is increased. Lifestyle modification is more effective mode of preventing diabetes and reduction of 40%-70% with pre-diabetes. While there is increasing evidence to prove the efficacy of pharmacotherapy in prevention of diabetes in adults with pre-diabetes, pharmaceutical treatment options other than metformin are associated with adverse effects that limit their use for pre-diabetes. It is considered to be an at risk state, with high chances of developing diabetes. While, pre-diabetes is commonly an asymptomatic condition, there is always presence of pre-diabetes before the onset of diabetes. This aim of this study is to describe the challenges associated with diagnosis of pre-diabetes, the possible adverse medical outcomes associated with pre-diabetes and the treatment options and rationale for their use in context of pre-diabetes. This research topic is selected for prevention of type 2 Diabetes Mellitus by identification of high risk subjects and early dietary intervention in the form of *Haridra*. Therefore, an attempt has been made to study the clinical efficacy of *Haridra* In *Prameha Purvaroop* W.S.R. To Prediabetes.

Key Words: Prediabetes, Diabetes, Prevention, *Prameha purvaroop, Haridra.*

Introduction

Diabetes is an "Iceberg" disease. Based on current estimates, increase in both the prevalence and incidence of type 2 diabetes mellitus have arisen globally. During year 2014, the number of cases of diabetes worldwide was estimated to be around 422 million. Of these, more than 90% are Type 2 Diabetes. In 2012, an estimated 1.5 million people died from consequences of high blood sugar levels. More than 80 % succumb to the complications due to Diabetes Mellitus in developing and poor countries. The prevalence of Diabetes globally was estimated to be 8.5% in adults aged more than 18 years. (1)

Diabetes is a non-communicable disease which is attaining increasing importance among the adult population in both developed and developing countries. The effect of chronic non-communicable diseases on the lives of people is serious when measured in terms of loss of life, disability, family poverty and economic loss to the country. In 2008, 57 million deaths occurred, out of these 36 million or 63 percent were due to non-communicable disease in which 3.5 percent deaths were due to Diabetes.(2)

India is facing a rapid health transition with a rising burden of non-communicable diseases causing significant morbidity and mortality, both in metropolitan and rural population, with considerable loss in potentially productive years (age 35-64 years) of life. In India non-communicable diseases are assessed to account for about 53 percent of all deaths.(2)

Unfavourable modification of lifestyle and dietary habits that are related with urbanization are believed to be the most important factors for the development of Diabetes. In urban areas the prevalence is approximately twice than that in rural areas.(1)

Diabetic patients, if undiagnosed or inadequately treated, develop multiple chronic complications leading to irreversible disability and death. Coronary heart disease and stroke are more common in patients of diabetes than in the general population. Micro vascular complications like diabetic nephropathy and diabetic neuropathy and retinopathy are serious health problems resulting in deterioration of the quality of life and premature death. In fact, diabetes is listed among the five most important factors of the cardiovascular disease epidemic in Asia. Lower limb amputation are at least 10 times more common in diabetic than in non-diabetic subjects in developed as well as developing countries, more than half of all non- traumatic amputations are due to diabetes. In pregnant woman diabetes diagnosed for first time during pregnancy

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carries a high health risk to both mother and foetus. The mortality due to diabetes among the people with diabetes is 1.5 to 2.5 times higher than in the general population.(1)

The population in India has an increased vulnerability to Diabetes mellitus. According to WHO the target population for screening of Diabetes in high risk groups. These groups are 1) those in the age group 40 years or more. 2) Those whose parents or siblings are Diabetic. 3) Those who are obese. 4) Woman who have or had a baby weighing more than 4.5 kg. 5) Women who show excess weight gain during pregnancy.(1)

Diabetes is a group of metabolic disorder characterized by a chronic hyperglycaemia condition resulting from insufficient action of insulin, impaired insulin secretion and increased insulin resistance.(3)

Diabetes mellitus is one of the most common chronic disease across the world and number of diabetic patients is on rise.(3)

Type 2 Diabetes Mellitus or non-insulin dependent diabetes mellitus account for at least 90% of all cases of diabetes. It is characterised by insulin resistance and relative insulin deficiency, either or both of which may be present at the time diabetes is diagnosed. Type 2 diabetes remain undetected for many years and the diagnosis is often made when a complication appears or a routine blood or urine glucose test is done.(3)

Diabetes Mellitus is a serious global health issue which has been encroaching on to the life of human beings and has made life miserable. The recently published Indian Council of Medical Research – INDIAB national study reported that there are 62.4 million people with type 2 diabetes and 77 million people with Pre- diabetes in India. The number of people with Pre- diabetes is increasing worldwide. In 2010 the prevalence of pre-diabetes was estimated at 344 million adults, this figure is expected to rise 472 million by 2030. (3)

Pre-diabetes is a precursor condition for type 2 Diabetes mellitus. Although in many cases it is reversible, Pre-diabetes frequently remains undiagnosed and therefore risk of developing type 2 Diabetes Mellitus is increased.

The risk factors for pre-diabetes are same as those for type 2 diabetes mellitus. An individual's risk factors for pre-diabetes include obesity, high waist circumference, family history of diabetes, hypertension, cardiovascular diseases etc. Pre-diabetes itself is a risk factor for type 2 Diabetes Mellitus.(4)

Therefore this research topic is selected for prevention of type 2 Diabetes Mellitus by identification of high risk subjects and early dietary intervention in the form of *Haridra.*

Haridra improves the β cell function of pancreas by preventing the β cell death. It reduces insulin resistance, which reduces the number of pre-diabetic individuals who progress towards type 2 Diabetes Mellitus. Therefore early diagnosis and prevention at proper time in Pre-diabetes by *Haridra* may prove beneficial to stop it from becoming type 2 Diabetes Mellitus.

In 13th chapter of *Sutrasthana* (*Agrya samgrahaniy*) of *Ashtangsamgraha Aacharya Vagbhat* mentioned that "*Haridra Pramehaharanam*".(5)

Aim and Objectives

Aim

To Study the Clinical Efficacy of Haridra in Prameha Purvaroop W.S.R. To Prediabetes.

Objectives

- To see the effect of *Haridra* in decreasing Blood Sugar Level(Fasting blood sugar and post prandial blood sugar).
- To assess the effect of *Haridra* in prevention of Diabetes.

Materials and methods

Patients with pre-diabetes were randomly selected from OPDs and IPDs of our institution.

Study was carried out in a single group in the before and after treatment form.

The diagnosed patients of pre-diabetes were taken according to IDRS (Indian Diabetes Risk Score) moderate score (30 to 50).

Study was carried out in *Swasthyarakshan* OPD of our institute and necessary follow up was carried out.

Total cost for investigations was bored by the investigator.

Those patients who developed Diabetes Mellitus during the study, were referred to *Kayachikitsa* Department for further treatment.

Type of Study:

This is an Interventional type of study.

Duration of Study:-

Total duration for this study was 3 months.

Sample Size:-

Prevalence rate of pre diabetes in Maharashtra is 12.8

$n=Z^2pq/E^2$

$n=3.84 \times 12.8 \times 87.2/(1.28)^2$

$=4286.05/1.63$

$=2629$

If $n=4pq/E^2$

$=4 \times 12.8 \times 87.2 /(1.28)^2$

$=4464/1.63$

$=2739$

Which is not feasible so n=66 was taken (taking 10% Drop out into consideration)

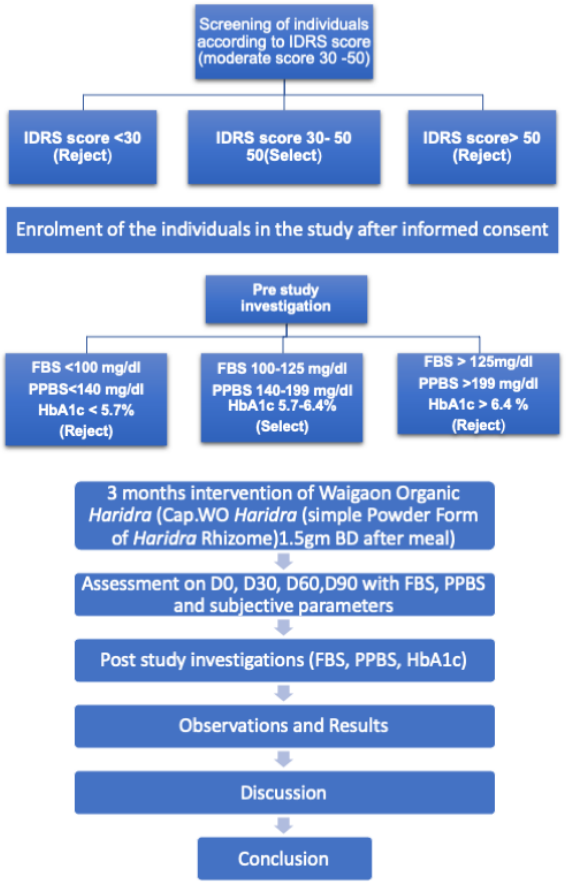
All these 66 individuals were advised to take capsule *Haridra* 1.5 gm twice a day after food

Preparation of Drug

- The drug used for the project was in the rhizome form. This rhizomes were dried and then powdered finely and made into capsule form.
- Authentication of *Waigoan* (Place-Taluka Samudrapur, Dist- Wardha) organic *Haridra* was

done by expert from *Dravyagun* Department of Research institute.
- Each capsule of 500 mg was prepared and then seal packed so that it could be easily handed over to the patient.
- Capsule *Waigoan* organic *Haridra* was prepared by standard preparation procedure in *Rasashastra* department of our institute.
- Standardization of *Haridra was done* from Government recognized lab.

Study Design



Inclusion criteria
- Diagnosed individuals of pre-diabetes according to IDRS (moderate score 30 to 50)
- Age group between 30 to 60 years.
- With no any other systemic disorder.
- Individuals of both sex.

Exclusion criteria
- IDRS > 60 and < 30.
- Individuals with age <30 yrs and >60 yrs
- Pre-diabetes with any other systemic disorder and complications.
- ANC and PNC
- Individuals undergone any major surgery.

Assessment criteria
Subjective parameter
***Purvaroop of Prameha*(5)**
- Sweda
- Aalasya
- Atinidra
- Talukanthashushkata
- Polyuria
- Polyphasia
- Polydipsia
- Polyneuritis

Swedpravritti
0 - Normal sweating
1 – Sweating which wets garments specially at axillary and groin region.
2 – Excessive sweating at axilla, groin and sweating at all over body.
3 - Profuse sweating

Aalasya
0- No *aalasya*
1- Not willing to do work
2- Can do routine work only when force to do so.
3-Cannot do routine work despite of force or pressure.

Atinidra
0- Normal 6 to 8 hrs.(at night)
1 - 8 to 10 hrs. (at night)
2 - 10 to 12 hrs. (at night & day)
3 ->12 hrs (at night & day)

4) *Talukanthashosh*:
0- No *talukanthashuskata.*
1- *Shuskata*which is relived after taking water.
2- *Shuskata* which is not relived after taking water.
3- *Shuskata* which is not relived after taking water persistently

Objective parameters

Indian Diabetes Risk Score	
Particulars	**Score**
1) Age:- a) <35 years b) 35-49 years c) >50 years	0 20 30
2) Waist circumference:- a) Waist< 80 cm(female) Waist <90 cm(male) b) Waist >80-89 cm(F) Waist >90-99 cm(M) c) Waist>90 cm(F) Waist >100 cm(M)	 0 10 20
3) Physical activities	
1. Vigorous exercise (regular) or strenuous (manual) work at home/work.	0
2. Moderate exercise (regular) or moderate physical activity at home/work.	10
3. Mild exercise (regular) or mild physical activity at home/work.	20
4. No exercise and sedentary activities at home/ work.	30

4) Family history of diabetes	
1.No diabetes in parents	0
2.One parent is diabetic	10
3.Both parent are diabetic	20

Score Calculation

- ≥60:-Very high risk of having diabetes.
- 30-50:- The risk of having diabetes is moderate.
- <30:- Risk of having diabetes is probably low.

Fasting blood sugar

- Normal: <100 mg/dl
- Pre-diabetes: 100-125 mg/dl
- Diabetes: >125 mg/dl

Post prandial blood sugar

- Normal: <140 mg/dl
- Pre-diabetes: 140-199 mg/dl
- Diabetes: >199 mg/dl

HbA1c

Normal: <5.7 %
Pre-diabetes: 5.7 to 6.4%
Diabetes: > 6.4

Diet and other advice

Diet

The routine diet of individuals were continued.

Place of work

Swasthyarakshan OPD, of our institution.

Ethical Clearance:-

Ethical clearance from Ethical committee of our institute was obtained before beginning of the research work.

Sampling Technique

Simple random method

Informed consent

Informed consent of each individual was taken

Observations and results

In this study 66 subjects with a single group of Pre-diabetes after the screening according to Indian Diabetes Risk Score were selected randomly as per selection criteria irrespective of sex, religion and socio-economic status. They were enrolled according to inclusion criteria and intervention was done before the start of treatment according to the case report form.

Subjects attending Outdoor Patient unit of Swasthavritta department in hospital were examined. After complete examination, subjects were recruited by allotting numbers from 1-66(considering dropouts). Capsule of *Waigaon* organic *Haridra* were prepared under the supervision of Head of department of *Rasashastra* and *BhaishajyaKalpana* of the institute. After completion of therapy all values of investigations and examinations were recorded and it was termed as after treatment values. All observations were statistically analyzed and results obtained are presented as below-

1) Total number of Subjects recruited in the study-66
2) Number of Subjects who completed the study-58

Reason for dropout – 6 subjects converted into diabetes and 2 subjects were given non compliance.

At the end of the study 58 subjects completed the study so statistical analysis for subjective and objective parameters is provided for the same i.e. 58 subjects.

Number of subjects enrolled in the study in the beginning and number of subjects dropped out are tabulated below.

Subjects enrolled in the study	Total
Subjects in the beginning of the study	66
Subjects dropped out	8
Subjects remained till the end of the study	58

Statistical Analysis of Subjective and Objective Parameters

Scores of Subjective and objective parameters were presented as Mean ± SD. Scores of Subjective parameters were compared between day 0 and day 90 by performing Wilcoxon sign rank test for non-normalized data. Objective parameters and Blood sugar level parameters were compared between day 0 and day 90 by performing paired t-test for normalized data. $p<0.05$ was considered as statistically significant. Statistical software STATA version 14.0 was used for data analysis.

Subjective Criteria

Table 1: Table Showing Comparison of Subjective Parameters at Day 0 and Day 90 (N=58)

Parameter	BT/AT	Mean	SD	Median	Range	% relief	Z-value	p-value
Sweda	**BT**	0.67	0.60	1	0-2	No change	-	-
	AT	0.67	0.60	1	0-2	No change	-	-
Aalyasya	**BT**	0.70	0.49	1	0-2	No change	-	-
	AT	0.70	0.49	1	0-2	No change	-	-
Atinidra	**BT**	0.31	0.53	0	0-2	No change	-	-
	AT	0.31	0.53	0	0-2	No change	-	-
Talukanthashushkata	**BT**	1	0	1	1-1	No change	-	-
	AT	1	0	1	1-1		-	-
Polyuria	**BT**	0.79	0.40	1	0-1	91.39	6.481	<.0001 HS
	AT	0.068	0.25	0	0-1			

Ploypasia	**BT**	0.43	0.49	0	0-1	69.77	4.123	<.0001 HS
	AT	0.13	0.34	0	0-1			
Polydipsia	**BT**	0.62	0.49	0	0-1	59.68	4.379	<.0001 HS
	AT	0.25	0.44	0	0-1			
Polyneuritis	**BT**	0.86	0.34	1	0-1	50.0	5.000	<.0001 HS
	AT	0.43	0.50	0	0-1			

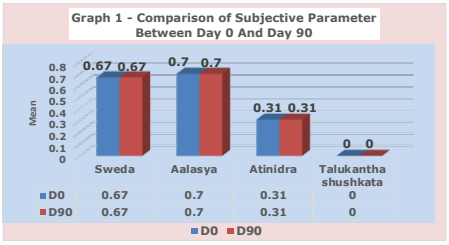
The above statistical result after application of the Wilcoxon sign rank test for subjective parameters before and after the treatment showed that there is no change in parameters of *Sweda, Aalyasya, Atinidra* and *Talukanthashushkata*. Whereas Polyuria, Polyphagia, Polydipsia and Polyneuritis relieved in a highly significant manner after the treatment. Since p-value of these four parameters was found to be less than 0.0001.

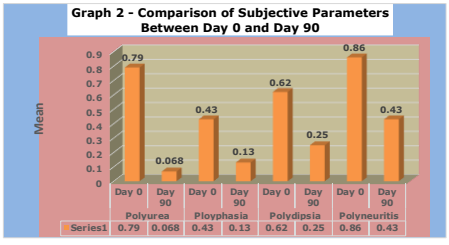
Objective parameters

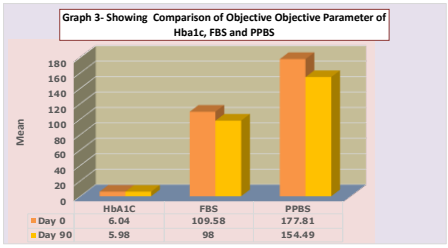
Table 2: Table Showing Comparison of Objective Parameters (Blood Sugar Level) at Day 0 and Day 90 (N=58)

Parameter	Day	Mean	S.D.	Median	Range	t-value	p-value
HbA1C	**BT**	6.04	0.34	5.9	5.5-7.4	1.1440	0.2574, NS
	AT	5.98	0.34	5.9	5.6-8.4		
FBS	**BT**	109.58	12.60	108	82-151	5.9641	<0.0001, HS
	AT	98.0	13.23	94	72-147		
PPBS	**BT**	177.81	23.23	179	119-227	7.0290	<0.0001, HS
	AT	154.49	29.12	147	108-272		

On comparing blood Sugar Level by applying paired t-test at day 0 and day 90 parameter HbA1C is found to be non-significant as p- value is 0.2574. Whereas after applying paired t-test to Fasting blood sugar and post prandial blood sugar the results revealed that there is very significant reduction was observed as p-value is<0.0001.







Discussion

Discussion on Selection of Topic

Diabetes Mellitus is one of the most common non communicable and chronic disease across the world and number of diabetic patients is on rise. Pre-diabetes is a precursor condition for type 2 Diabetes Mellitus. Pre-diabetes remains undiagnosed and definitely transform into Diabetes Mellitus. The number of people with pre-diabetes is increasing worldwide and risk factor for pre-diabetes are same as those for type 2 diabetes mellitus. In *Ayurvedic* texts *Prameha* is considered as Diabetes Mellitus and *Prameha Poorvaroopa* considered as Pre-diabetes. There are many drugs explained in *Ayurvedic* texts for *Prameha Chikitsa*. *Haridra* is one of the best drug (*agrya*) explained in *Agryasamgrahaniya Adhyay* of *Ashtangsamgraha*. In this study, the drugs selected belong to one of the *Aahaar Vargas* and hence are completely free from side-effects and being a dietary supplement, it can be used for a long period of time. Taking all the above view in consideration, it was thought in mind to evaluate the effect of this drug as a dietary supplement to achieve the goal of preventing Diabetes Mellitus in pre-diabetic stage as a risk factor for diabetes.

Discussion on Plan of the Study

The study was conducted in a pre-post evaluation method with a single group of total 66 Subjects. Subjective and objective parameters were assessed before and after the study. The study was carried out in the dept. of *Swasthyarakshan* of our institute. Subjects of Pre-diabetes were screened as per the Indian Diabetes Risk Score, irrespective of their sex, religion, socio-economic status and educational status. After screening those subjects who were at high risk of Diabetes were done blood sugar level. After that those subjects who were in Pre-diabetic range according to blood sugar level were enrolled in the study. Chief complaints, vital examination, Family history of Diabetes, history of any medication in the past were recorded as per the Case report form. All the subjects were clinically examined by using modern as well as *Ayurevedic* parameters. No change done in diet and exercise, routine diet was advised.

Discussion on Drug Formulation

The powdered form of *Waigaon* organic *Haridra* standardized by *Dravyaguna* dept. of our institute and capsule were prepared under the supervision of head of department of *Rasashastra*. Each capsule was prepared

with 500 mg of *Haridra* powder. Drug was administered 1.5 gm twice a day after meals for three months and follow up was taken at 30th, 60th and 90th day. On each follow up, subjects were evaluated according to case report form attached in this dissertation annexure. This data obtained was termed as AT (after treatment) value. All the observations and results obtained are described here as below.

Discussion on Objective Parameter

Effect on HbA1c, FBS and PPBS

By applying paired – t test the mean value of HbA1C before treatment was 6.04 which reduced to 5.98 after treatment. Which is found to be statistically non-significant because t-value is 1.1440 at p – 0.2574. Hence it indicates that effect of drug *Haridra* showed non–significant effect on HbA1C. This shows that the HbA1c values of the subjects were reduced but not significantly because HbA1C value is an average value of glycosylated haemoglobin of the past 3 months.

By applying paired t-test the mean value of FBS before treatment was 109.58 which reduced to 98.0 and the mean value PPBS was 177.81 before the treatment which reduced to 154.49 after the treatment. Which is found to be statistically highly significant because p-value is < 0.0001 in both the parameter. Hence it indicates that effect of drug *Haridra* showed highly significant result in reducing the blood sugar level i.e. Fasting and post prandial blood sugar level.

Haridra, due to its *Katu-Tikta Rasa, Ruksha* and *Laghu Guna, Ushna Veerya* and *Katu Vipaka* because of this properties effectively destroys the contaminated *Kapha* which is primary culprit in the manifestation of Prameha. All these properties are antagonistic to the properties of *Kapha*. This might be the reason for broken down the pathology of Prameha wherein the disease is showing the signs of progression in Pre-diabetes.

Discussion on Subjective Parameter

Parameters like *Sweda, Aalyasya, Atinidra* and *Talukanthashushkata* were also studied and it was observed that there was no change before and after the treatment in the subjects. Because the grade of all parameters were same as before and after the treatment. Comparing the change before and after the treatment by applying Wilcoxon rank signed test there is no change after the completion of study, because this test showed no statistical significance. It indicates that drug *haridra* is not effective in reducing the symptoms of *sweda, aalyasya, atinidra* and *talukanthashushkata.*

After applying the non-parametric test like Wilcoxon sign rank for polyuria symptom, by comparing before and after the treatment it is observed that 91.39 % of the subjects have reduction in symptoms. As p-value is < 0.0001 it is highly significant change. Hence, it indicates that *Haridra* is very effective in reducing the symptoms of polyuria of pre-diabetes.

After applying the non-parametric test like Wilcoxon sign rank for polyphagia symptom, by comparing before and after treatment it is observed that 69.77 % of the subjects have reduction in symptoms. As p-value is < 0.0001 that is highly significant change. Hence, it indicates that *Haridra* is very effective in reducing the symptoms of polyphagia of pre-diabetes.

After applying the non-parametric test like Wilcoxon sign rank for polydipsia symptom, by comparing before and after treatment it is observed that 59.68 % of the subjects have reduction in symptoms. As p-value is < 0.0001 that is highly significant change. Hence, it indicates that *Haridra* is very effective in reducing the symptoms of polyphagia of pre-diabetes.

After applying the non-parametric test like Wilcoxon sign rank for polyneuritis symptom by comparing before and after treatment observed that 50 % reduction. As p-value is < 0.0001 that is highly significant change. Hence, it indicates that *Haridra* is very effective in reducing the symptoms of polyneuritis of pre-diabetes.

Above data shows that there is highly significant changes before and after the treatment in reducing the symptoms like polyuria, polyphagia, polydipsia and polyneuritis. It might be because of drug *Haridra* contain the properties like *Katu, Tikta Ras, Ushna Veerya, Katu Vipak* and *Kaphaghna*. Because of these properties *Kapha Dosha* that increased in *Prameha Purvaroopa*(Pre-diabetes), *Haridra* is useful in reducing that vitiated *Kapha* and breakdown the pathophysiology of *Prameha*.

Conclusion

Following conclusions can be drawn from this study.

- *Haridra* is helpful in decreasing the blood sugar level i.e. fasting blood sugar level and post prandial blood sugar level in Pre-diabetes.
- *Haridra* is helpful in decreasing the symptoms like polyuria, polyphagia, polydipsia and polyneuritis.
- *Haridra* is not helpful in decreasing the HbA1c level in Pre-diabetes.
- Action of *Haridra* in decreasing the blood sugar level and symptoms of Pre-diabetes is because of-
- In *Prameha Purvaroopa* there is predominance of *Kapha Dosha*. The disturbance of *Kapha* prepares a suitable environment in the body for the manifestation of *Prameha*.*Haridra*, due to its *KatuTikta Rasa*, *Ruksha* and *Laghu Guna*, *Ushna Veerya* and *Katu Vipak* effectively destroys the contaminated *Kapha* which is the primary culprit in the manifestation of *Prameha*. All these properties are antagonistic to *Kapha*. This *Kapha* alleviating property of *Haridra* is especially effective in the Pre-diabetic condition.
- Taking control of this stage helps in arresting the disease before it progresses to the complicated stages. Thus *Haridra* is proves to be useful in Pre-diabetic stage, and in prevention of diabetes.

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