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CLINICAL TRIAL TO EVALUATE THE EFFICACY OF JALA BASTI IN PROPHYLAXIS OF PREDIABETES

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ABSTRACT

Pre-diabetes/ intermediate hyperglycaemia grounded on glycaemic variables above normal range but under diabetes thresholds. The prevalence of pre-diabetes is surging all over the world and it is estimated that >470 million people will develop pre-diabetes in 2030. Lifestyle modification is the mainspring of diabetes prevention with documentation of a 40%–70% relative risk reduction. So, open clinical trial on an Ayurvedic intervention *Jala basti* was planned in prophylaxis of Pre-diabetes. Aim of the trial was to evaluate the effect of *Jala Basti* in prophylaxis of Pre-diabetes. 40 Pre diabetic Patients who were willing for trial, aged between 20-70 years of either sex, having Hemoglobin A1C range between 5.7% to 6.4%, FBG (fasting blood glucose) range 100 mg/dl to 125 mg/dl, OGTT (Oral glucose tolerance test 2 hour blood glucose) range between 140 mg/dl to 199 mg/dl, RBS (random blood sugar level) greater than or equal to 200 mg/dl were selected from OPD and IPD of Dept. Of *Swasthwrita*, Hospital of Uttaranchal Ayurvedic Collage, Uttarakhand Ayurved University, Dehradun. Patients below age of 20 years and above 70 years of age, all type 1 and type 2 Diabetes mellitus cases and cases with complications of the disease or having other associated disease were excluded from trial. The assessment of relief in Blood sugar fasting, RBS, OGTT, HBA1C has been shown as 12.24%, 16.27%, 14.36% and 3.8% relief respectively. The p value for all these is <0.01 which is statistically significant. It can be concluded that *Jala basti* can be effective prophylactic mode in the management for pre-diabetes. So for better understanding of efficacy of *Jala vasti*, clinical trial with more patients and more diagnostic tools can be carried out.

INTRODUCTION

Pre-diabetes/ intermediate hyperglycaemia grounded on glycaemic variables above normal range but under diabetes thresholds.

The overall prevalence of diabetes was 6.65% and pre-diabetes was 5.57%.[1] The prevalence of pre-diabetes is surging worldwide and it is estimated that >470 million people will develop pre-diabetes in 2030. Pre-diabetes has synchronus existence of insulin resistance and β-cell dysfunction, malformation that start before glucose changes are evident. Pre-diabetes has inter-realtion of early forms of nephropathy, chronic kidney disease, small fibre neuropathy, diabetic retinopathy, and increased risk of macrovascular disease.[2] Pre-diabetic persons exhibit high level of depression and thus scored high on depression scale. The pre-diabetic group despite medication might not be free from all physical or psychological troubles.[3]

It is estimated that almost 5-10% of people with pre-diabetes progress to type-II diabetes and converting back to normoglycaemia every year.[2] Lifestyle modification is the mainspring of diabetes prevention with documentation of a 40%–70% relative risk reduction. So, trial on an Ayurvedic intervention *Jala basti* was planned in prophylaxis of Pre-diabetes.

Term pre-diabetes as disease entity is not mentioned in Ayurvedic literature but on the basis of similarity of etiopathogenesis, clinical features, complications and management of prediabetes, it can be correlated with *poorvaroopa* of *Prameha*. *Jala vasti* is mentioned in treatment of *Prameha* in *Gherand Samhita*.[4]

MATERIAL AND METHODS

Aim: To evaluate the effect of *Jala Basti* in prophylaxis of Pre-diabetes.

Trial type: Open clinical trial study.

Criteria for Selection of Patients

Pre diabetic Patients who were willing for trial, aged between 20-70 years of either sex, having Hemoglobin A1C range between 5.7% to 6.4%, FBG (fasting blood

glucose) range 100 mg/dl to 125 mg/dl, OGTT (Oral glucose tolerance test 2 hour blood glucose) range between 140 mg/dl to 199 mg/dl, RBS (random blood sugar level) greater than or equal to 200 mg/dl were selected from OPD and IPD of Dept. Of *Swasthwrita* and *Panchakarma*, Hospital of Uttaranchal Ayurvedic Collage, Uttarakhand Ayurved University, Dehradun. There after the patients were subjected for detailed clinical history & physical examination.

Exclusion Criteria

Patients below age of 20 years and above 70 years of age, all type 1 and type 2 Diabetes mellitus cases and cases with complications of the disease or having other associated disease were excluded from trial.

WITHDRAWAL CRITERIA

1. Personal matters
2. Inter-current illness
3. Aggravation of complaints
4. Patient develops any serious adverse effect (necessitating hospitalization)

STUDY METHODOLOGY

Demographic data was collected from the registered patients along with baseline assessment according to the proforma. Assessments of the patients were done before treatment and after 30 days of treatment. After completion of therapy, patient was advised to visit OPD after one month.

All 40 patients were administrated with *Jala Basti. Jala Basti* was given in the morning for 30 days. From patients, written informed consents were taken before entering into study. The importance of them for adherence to the treatment, *Pathya-Apathya* associated with the disease, schedule for follow up, dates for visits to hospital was issued.

RESULTS AND DISCUSSION

The assessment of relief in Blood sugar fasting, RBS, OGTT, HBA1C has been shown in the data as 12.24%, 16.27%, 14.36% and 3.8% relief respectively. The p value for all these is <0.01 which is statistically significant.

Table 46: Comparison of Parameters In Patients Before and After Treatment.

PARAMETERS	MEAN ±SD			P value	Significance
	BT	AT	% Change		
Blood sugar fasting (FBS)	113.58 ±7.78	99.68 ±8.07	12.24%	<0.01	Significant
RBS	208.65 ±8.59	174.7 ±19.01	16.27	<0.01	Significant
OGTT	165.38 ±16.73	141.63 ±20.04	14.36	<0.01	Significant
HBA1C	5.78 ±0.43	5.56 ±0.45	3.80	<0.01	Significant
Paired t test is used (p value less than 0.01 is significant)					

The follow up assessment of Blood sugar fasting, RBS, OGTT, HBA1C has been shown in the data as 16.09%, 15.35%, 8.21% and 3.38% relief respectively. The p value for all these parameters is <0.01 which is statistically significant.

Parameters	MEAN ± SD		% Change	p – value	significant
	BT	FU			
Blood sugar fasting (FBS)	113.58 ±7.78	95.3 ± 23.08	16.09%	P<0.01	Significant
RBS	208.65 ±8.59	176.63 ± 23.08	15.35%	P<0.01	Significant
OGTT	165.38 ±16.73	151.8 ± 16.78	8.21%	P<0.01	Significant
HBA1C	5.78 ±0.43	5.58 ± 0.41	3.38%	P<0.01	Significant
Paired t test is used (p value less than 0.01 is significant)					

DISCUSSION

Aptarpan chikitsa is mentioned for this type of metabolic state of diseases. According to *Acharya Vagbhat, Aptarpana* is of two types- *Shodhana and Shamana. Basti Chikitsa* comes under *Shodhana. Basti* comes under the *Panchshodhana* of *Aptarpana*. *Jala Basti* can be considered under the *Niruha Basti* on the basis of quantity and other factors. *Jala Basti* is mentioned in *prameha* which we have used in *poorvaroop*a(~prediabetes) like condition.

Prameha comes under the *Kaphaja Roga. Acharya Kashyapa* explained that the disease in which there is *Kapha samsrushta (~association)* and *Vata* is not *prabala(~high), Basti* can be planned. Thus, it can helps in the prophylactic management of this disease reversing the pathological conditions.

Basti after entering into *Pakvashaya* or *Guda* acts on whole body. *Guda* is *Sharira Mul*a having many *Shira* and *Dhamani*, which are connected to whole body. *Jala Basti* is capable of removing the *Doshas* from whole of the body. Thus, in short, *jala Basti* given in *Pakvashaya* act through spreading of *Virya* of the *Basti* in the entire body by *Acharya Sushruta*.

Jala of Basti reaches at ileo-caecal junction due to quantity and firm pressure applied and then returns back to be eliminated out. As *Basti* is administered high in the rectum and usually carried directly to the liver and thus are subject to metabolism. *Basti* which is instilled low in the rectum are delivered systematically by the inferior and middle rectal veins before passing through the liver. *Basti* break down the *Dosha Sanghata* in *Srotas*, thus it help in removing *Sanga* in *Srotas.* By removing *Sanga* it keeps *Sanchrana Marga* of *Vyana Vayu* in normal condition. Thus *Vyana Vayu* can transport the nutrient to its related *Dhatu* and *Uttrotar Dhatu Nirmana* takes place properly.

There are many theories[5] regarding *Vasti* which we can use to understand the mode of action of *Jala Basti*. The most applicable theories are Neural stimulation mechanism, Excretory mechanism and by absorption mechanism.

Neural stimulation mechanism work like that- Lukewarm water given through anal route has done the stimulation of Enteric Nervous System which leads to excitation of mysentric plexus and submucosal plexus. Neurotransmitters carry information to CNS and CNS acts independently to produce the effect. So through this mechanism, prediabetes where there is involvement of psychological factors can be resolved. All these factors are compensated by *Jala Vasti* understood by gut-brain axis mechanism.

Effect of *Jala vasti* through excretory mechanism can be understood like this- When high quantity of water are made entered through anal route, hyper osmosis takes place from colon cells to lumen, since the water is lukewarm so, absorption of endotoxins leading to irritation of large intestine (due to mild irritant property) and hence excretion of toxins (*Dosha*, *Mala*).

Effect of *Jala vasti* through absorption mechanism can be understood as- Absorption by the superior haemorrhoidal veins occur and reaches directly to liver & 2/3rd directly enters systemic circulation, significant availability of drugs bypassing first pass metabolism, correcting the liver metabolism and rectifying mechanism of glucose metabolism & increasing excretion into intestine and ultimately to relief as resulted.

Rectal administration provides rapid absorption of the drugs. The rate of rectal transmucosal absorption is affected by following factors: Quantity and temperature of water, length of rectal catheter, presence of stool in the rectal vault, pH of the rectal contents, rectal retention of *Vasti* administrated, differences in venous drainage within the recto-sigmoid region.
Impaired blood sugar levels are because of *dhatus dusti*, *ama* formation rectified by *Vasti* as shown in results. *Jala basti* (lukewarm) removes the obstruction in channels. So, it might act in reduction of insulin resistance leading to better glucose absorption and utilization as postulated in present study.

CONCLUSION

It can be concluded that *Jala basti* can be effective prophylactic mode in the management for pre-diabetes. Large sample size can postulate this fact more clearly. So for better understanding of efficacy of *Jala vasti*, clinical trial with more patients and more diagnostic tools can be carried out.

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