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Research Article

A COMPARATIVE CLINICAL EVALUATION ON THE EFFICACY OF *KUBERAKSHA* & *YAVA* WITH LIFESTYLE MODIFICATION, IN THE MANAGEMENT OF *PRAMEHA* WITH SPECIAL REFERENCE TO PREDIABETES

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ABSTRACT

We are living in the age of complexity, contradiction, and challenge relating to various health issues such as lifestyle disorder, ageing, mental health euthanasia, drug resistance and so on. Diabetes Mellitus is a Giant disease and major health issue that has reached alarming level in spite of terrific advance in modern medical science. Prediabetes is the precursor stage before Diabetes Mellitus, in which not all of the symptoms required to diagnose diabetes are present, but blood sugar is abnormally high. Prediabetic persons are considered to be at increased risk for the subsequent development Diabetes Mellitus. Sushruta Samhita mentioned, all varieties of *Prameha* if not treated at appropriate time, become changed to *Madhumeha* which is incurable. So, early detection, treatment and prevention of this disease in Prediabetic stage is needed. The modification of lifestyle should be the first aim and objectives to restrict or combat such problems, beside this prime objective, some medication which is safe and efficacious to be introduced. So, a clinical study with 60 patients has been conducted on Prediabetes through the management with *'Kuberaksha'* and *'Yava'* in such 2 groups of treatment. The two drugs are carrying such properties which acts in *Samprapti vighatana* (prevent pathogenesis) of the disease. In both cases statistically significant results are found (P<0.001 & <0.01). On comparison between two groups *Kuberaksha* powder showed better result than *Yava* powder.

INTRODUCTION

In Ayurvedic compendium, the disease *Prameha* has been described with great importance. It has been mentioned under *'Astha Mahagada'* (eight disease of great importance)[1]. It has also been mentioned as foremost *'Anushanga Vyadhi'* (relapsing disease)[2]. In the recent reports it is stated that, Prameha in term of Diabetes is the eighth leading cause of death in worldwide in 2012 [3]. More than 422 million people are suffering from this disease throughout the world in 2014 [4].

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The International Diabetes Federation has estimated the number of diabetes patient in India is 61.3 million (2011) which is projected to be 101.2 million on 2030 [5]. That's why WHO has declared in the year 2014 that 'India is the Diabetes Capital of The World' [6]. The main etiopathogenesis of *Prameha* in general addiction to the pleasure of sedentary habits, sleep, curds, soup of meat of domesticated and aquatic animal, milk preparations and like all others *Kapha* aggravating factors increases the watery parts (*Drava guna*) of *Kapha* which causes *Agnimandya* and produces *'ama'*, this *ama* entered into the *Shrotas* as *kledas* and flows to *Mutrvaha shrota* as well as visit *vasti* for its '*Drava* and *Sarana*' *guna*. Simultaneously other parts of '*ama*' gets entry to the other *Dhatus* and dearranged the '*Dhatwagni paka'*, which leads to *Bahubaddha meda* and *Mamsa dhatu* in the system in general. In pathogenesis more or less each body elements is involved concluding the disease of vast systemic consideration.

The US Department of Health and Human Services' and 'American Diabetes Association' on 27th march 2002 gave the term 'Pre-diabetes'. The term 'increased risk for Diabetes' (ADA) and 'intermediate Hyperglycaemia' (WHO) used rather than Prediabetes [7]. Pre-diabetes is a condition in which individuals have blood glucose level higher than normal but not high enough to be classified as diabetes. An estimated 34% of adults have pre-diabetes. If left untreated 37% of the individuals with pre-diabetes may have diabetes in 4 years. [8]. ADA criteria for diagnosis of Prediabetes are, FBS 100-125 mg/dl, PPBS 140-199 mg/dl and HbA1c 5.7-6.4 [9]

In *Prameha* there is predominance of '*Kapha*' among *Tridosha* and '*Meda*' among 10 *Dushyas*. *'Kuberaksha'* having *Tikta-kasaya* rasa, *Katu vipak* and *Tridosha hara* property, its seed contains flavonoids, triterpenoids and steroid which act as an antioxidant and free radical scavengers and responsible for anti-diabetic action, additionally its *Ushna virya* will be able to enhance *agni* by reducing the *Kapha*. On the other hand, *'Yava'* having properties like *Kapha-pitta prasamana*, *Lekhana, Medohara,* and *Dhatwagni bardhak*. In *Prameha* the *Dhatwagni paka,* specifically the activity of *Medagni* gets destroyed, which are very much essential for generation of *Agni*. It reduces the *Apa* and *Prithvi Mahabhuta* which are the main components of *Meda dhatu*, so in analogous action they diminish *Meda dhatu* and clear the Channels, and further transportation to deeper *Dhatus* occurs.

Modern hypoglycemic drugs are useful in the treatment of diabetes but restricted by the pharmacokinetic properties, secondary failure rate & side effects [10]. So, the present clinical study (Research work) may through a new light to the field of management of Prediabetes and prevention of *Madhumeha*.

AIM & OBJECTIVES

1. Identify interventions to modify risk factors for prevention of *Madhumeha* (Diabetes & its complications).
2. To re-evaluate the concept of *prameha* and pre-diabetes as per Ayurvedic and Western literature. And to evaluate the effect of *'Kuberaksha'* and *'Yava'* in biochemical parameters.
3. To develop a strategic management plan for patient with prediabetes.
4. To observe any side-effects during the therapy.
5. To encourage the future workers in this field for diagnosis and better management of this disease.

MATERIAL AND METHODS

Place of study

The present study was conducted in Institute of Post Graduate Ayurvedic Education & Research at S.V.S.P Hospital, 294/3/1, APC Road, Kolkata-700009, in the Department of Kayachikitsa. The study was approved by the institutional ethical committee and procedures were in accordance with the ethical standards of the responsible committee on human experimentation.

Material

1. *Kuberaksha* (*Caesalpinia bonducella*)
2. *Yava* (*Hordeum vulgare*)

Sample Design

Group A	30 patients were included in this group with oral drug under coverage of prescribed *Pathya* and *Apathya*. Treated with *Kuberaksha* seed powder 2 gm BD, Before lunch, twice daily with water for 3 months.	
Group B	30 patients were included in this group with oral drug under coverage of prescribed *Pathya* and *Apathya.* Treated with *Yava* powder 10 gm BD, twice daily with water for 3 months.	

Sample Size: Sixty Patients (60)

Period of Study: 1 and ½ years (18 months)

Individual patient 90 days.

Selection Criteria

Inclusion Criteria	Exclusion criteria
1. Age between 25-40 years, both sexes. 2. Patients, willing to take part of study. 3. FBS: 110-125 mg/dl. 4. PPBS: 140-199 mg/dl 5. Family history of Type-II DM.	1. Age below 25 years and above 40 years. 2. Alcohol addiction. 3. Major medical or surgical diseases like CKD, CVD, CVA, DKA, Hypertensin, Psychiatric problem etc. 4. Pregnant and lactating mother. 5. Not willing to given consent. 6. Patient on treatment developing side-effects.

Laboratory Investigations: FBS, PPBS, Serum Urea, Serum Creatinine.

Diagnostic Criteria

Subjective Criteria	Objective Criteria
1. Alasya 2. Karapadadaha. 3. Pipasadhikya 4. Swedatipravritti. 5. Shitapriyata. 6. Madhuramasya. 7. Swapnasukha	1. FBS. 2. PPBS.

Assessment Criteria: Subjective Parameters

Subjective Parameters	Findings	Scoring
1. *Alasya* 2. *Karapadadaha* 3. *Pipasadhikya* 4. *Swedatipravritti* 5. *Shitapriyata* 6. *Madhuramasya* 7. *Swapnasukha*	None	0
	Mild	1
	Moderate	2
	Severe	3

Objective Parameters

S.No.	Objective Parameters	Range	Scoring
1.	FBS	< 110	0
		110-115	1
		116-120	2
		121-125	3
2.	PPBS	<140	0
		140-159	1
		160-179	2
		180-199	3

Assessment of overall effect

1.	Complete remission	100% relief in sign and symptoms
2.	Marked improvement	≥75% to <100% relief in sign and symptoms
3.	Moderate improvement	≥50% to <75% relief in sign and symptoms
4.	Mild improvement	≥25% to <50% relief in sign and symptoms
5.	Insignificant Improvement	<25% relief in sign and symptoms

Statistical Analysis

The obtained data were analyzed statistically. The values were expressed as Mean ($\bar{X}$) ± SEM (Standard Error of Mean). The data were analyzed by Paired 't' test. A level of $p < 0.001$ were considered as statistically highly significant and $p < 0.05$ were considered as statistically significant. Level of significance were noted and interpreted accordingly.

OBSERVATIONS AND RESULT

All the patients of this study were registered in a specialized research format with their informed consent. The clinical trial was conducted and the observation were discussed under the Demographic profile, Clinical profile, Laboratory profile and Therapeutic profile in 60 patients.

Demographic Profile in 60 Patients

- ✓ **Age:** Maximum patients were recorded in the age group of 36-40 years (50%).
- ✓ **Sex:** Majority of the patients were male (60%).
- ✓ **Marital Status:** 83.33% of the patients who have undergone this study were married.
- ✓ **Occupation:** Maximum (35%) were involves in business, 30% were involves in domestic household chores, 16.67% were involved in some kind of service, 8.33% were tailor, 5% were labors, on daily wages or in factories as well, and 5% was student.
- ✓ **Socio-Economic Status:** 58.33% of the patients were belong to the middle class, while 33.33% of the patients were in lower class and 8.33% of the patients was from upper class of the society.

Clinical Profile in 60 Patients

- ✓ **Dietary Habit:** maximum patients (58.33%) were having *Visamasana,* followed by 21.67% *Adhyasana,* 11.67% *Samasana* and rest of the 8.33% were having the habit of *Alpasana.*
- ✓ **Body Weight:** most of the patients (35 Patients) were having normal body weight (58.33%), 21 patients were having over weight (35%) and rest of the 4 patients (6.67%) were under weight.
- ✓ **Dominant Rasa in diet:** Analysis on the basis of dominant rasa in the diet showed that maximum patient had inclination for Madhura rasa (51.67%) followed by Amla rasa (18.33%), Lavana rasa (13.33%), Katu rasa (6.67%), Tikta rasa (6.67%), Kasaya rasa (3.33%).
- ✓ **Sleeping Habit:** Table shows that 38.33% of the patients were having less sleep, 36.67% were having disturbed sleep and 25% having normal sleep.
- ✓ **Day Sleep:** 31 patients (51.67%) were having daily day sleep, followed by 15 Patients (25%) were having occasional day sleep and 14 patients (23.33%) never had day sleep.
- ✓ **Nature of work:** 31 patients (51.67%) had sedentary lifestyle whereas 23 patients (38.33%) had Active work and 6 patients (10%) hav heavy work in their schedule.
- ✓ ***Sharira Prakriti:*** Only *dwandaja Prakriti* were found in this observation, of which 43.33% were *pitta-kapha prakriti*, while 33.33% were *vata-kaphaja prakriti* and 23.33% were found to having *vata-pitta prakriti*.
- ✓ **Family History:** maximum number of patients i.e. 43 patients (71.67%) had family history of Prameha and 17 patients (28.33%) had no family history of Prameha.

Table 1: Showing Chief complaint of Both Groups

S.No.	Chief Complaint	No. of Patients		Total	Percentage
		Group A	Group B		
1.	*Alasya*	29	28	57	95%
2.	*Kara-pada daha*	20	19	39	65%
3.	*Pipasadhikya*	18	17	35	58.33%
4.	*Swedatipravritti*	24	22	46	76.67%
5.	*Shita priyata*	14	16	30	50%
6.	*Madhuram-asya*	26	20	46	76.67%
7.	*Swapnasukha*	24	19	43	71.67%

Laboratory Profile in 60 Patients

Table 2: Showing FBS of the 60 Patients

S.No.	FBS	No. of Patients		Total	Percentage
		Group A	Group B		
1.	110-115 mg/dl	06	08	14	23.33%
2.	116-120 mg/dl	09	10	19	31.67%
3.	121-125 mg/dl	15	12	27	45%

Table 3: Showing PPBS of the 60 Patients

S.No.	PPBS	No. of Patients		Total	Percentage
		Group A	Group B		
1.	140-159 mg/dl	04	07	11	18.33%
2.	160-179 mg/dl	10	10	20	33.33%
3.	180-199 mg/dl	16	13	29	48.33%

Table 4: Showing Serum Urea of the 60 Patients

S.No.	Serrum Urea	No. of Patients		Total	Percentage
		Group A	Group B		
1.	10- 15 mg/dl	10	06	16	26.67%
2.	16-20 mg/dl	07	11	18	30%
3.	21-25 mg/dl	10	07	17	28.33%
4.	26-30 mg/dl	03	06	09	15%

Table 5: Showing Serrum Creatinine level of the 60 Patients

S.No.	Serrum Creatinine	No. of Patients		Total	Percentage
		Group A	Group B		
1.	0.5-1.5 mg/dl	30	30	60	100%
2.	>1.5 mg/dl	00	00	00	0%

Table 6: Showing LFT of the 60 Patients

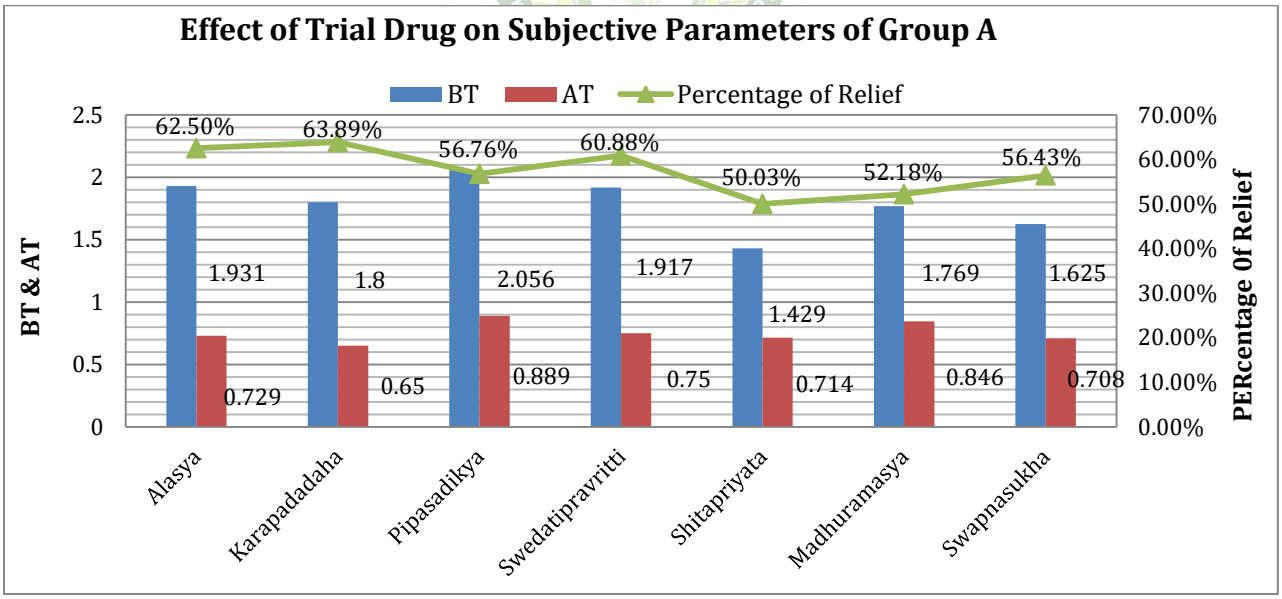
S.No.	LFT	No. of Patients		Normal Range
		Group A (Mean)	Group B (Mean)	
1.	Billirubin (mg/dl)	0.50	0.48	0.2-1.2 mg/dl
2.	SGOT/AST (IU/L)	23.70	21.93	8-54 IU/L
3.	SGPT/ALT (IU/L)	28.07	31.13	7-56 IU/L
4.	ALP (IU/L)	68.10	66.70	44-147 IU/L

Observation on Therapeutic Trial:

n= Number of Patients, BT= Before Treatment, AT= After Treatment, MD= Difference in Mean, SD= Standard Deviation, SE= Standard Error, 't'= Paired t test, 'p'= Level of Significance

Table 7: Effect of Trial Drug on Subjective Parameters of Group A Patients

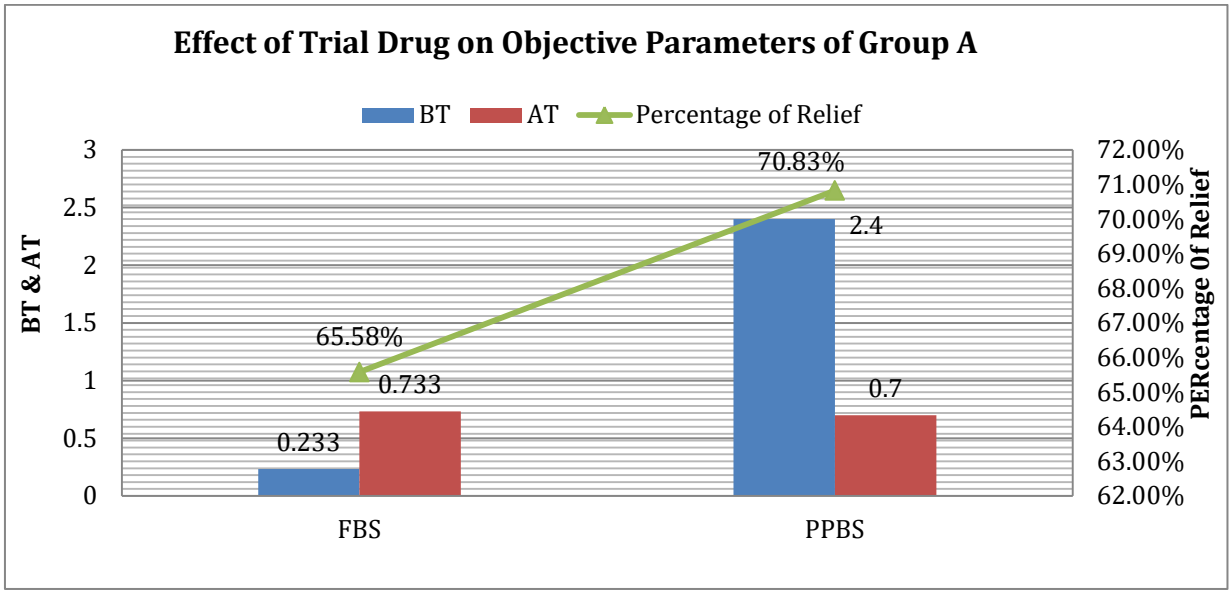
Subjective Parameters	n	Mean Score		MD	% of Relief	SD (±)	SE (±)	't' Value	'p' Value
		BT	AT						
Alasya	29	1.931	0.724	1.207	62.50%	1.346	0.250	4.83	<0.001
Karapada daha	20	1.8	0.65	1.15	63.89%	1.089	0.244	4.71	<0.001
PipasaAdhikya	18	2.056	0.889	1.167	56.76%	1.098	0.259	4.51	<0.001
Swedatipravritti	24	1.917	0.75	1.167	60.88%	1.239	0.253	4.61	<0.001
Shitapriyata	14	1.429	0.714	0.715	50.03%	0.611	0.163	4.39	<0.001
Madhuramasya	26	1.769	0.846	0.923	52.18%	0.977	0.192	4.80	<0.001
Swapnasukha	24	1.625	0.708	0.917	56.43%	0.974	0.199	4.60	<0.001



Graph 1: Effect of Trial Drug on Subjective Parameters of Group A

Table 8: Effect of Trial Drug on Objective Parameters of Group A Patients

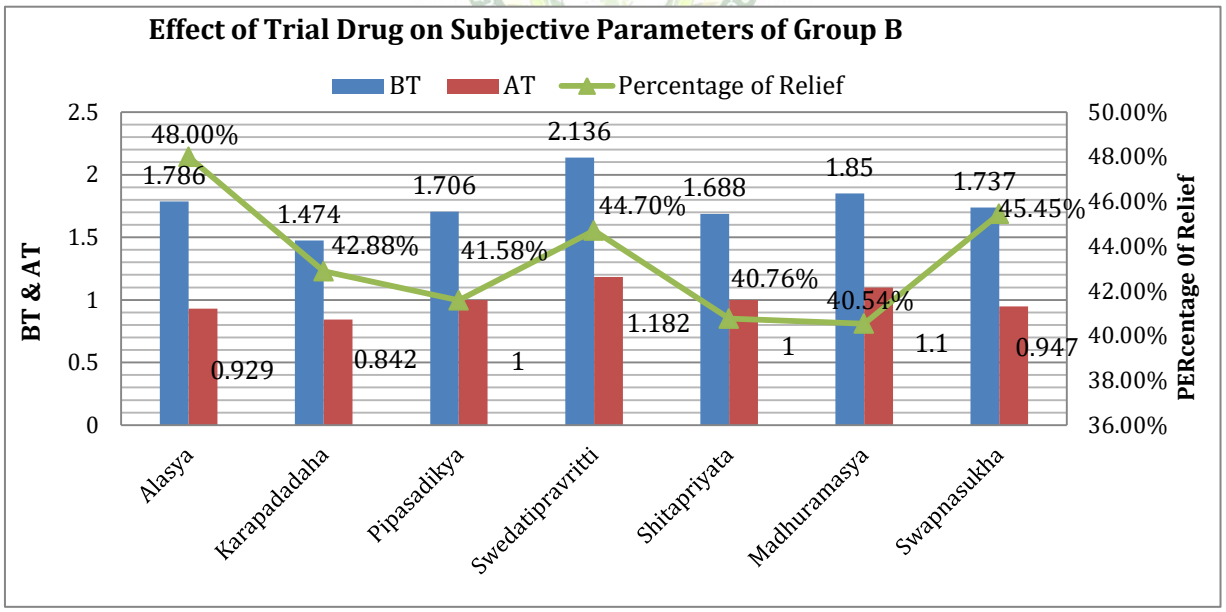
Objective Parameters	n	Mean Score		MD	% of Relief	SD (±)	SE (±)	't' Value	'p' Value
		BT	AT						
FBS	30	0.233	0.733	1.6	65.58%	1.404	0.256	6.25	<0.001
PPBS	30	2.4	0.7	1.7	70.83%	1.393	0.254	6.68	<0.001



Graph 2: Effect of Trial Drug on Objective Parameters of Group A

Table 9: Effect of Trial Drug on Subjective Parameters of Group B Patients

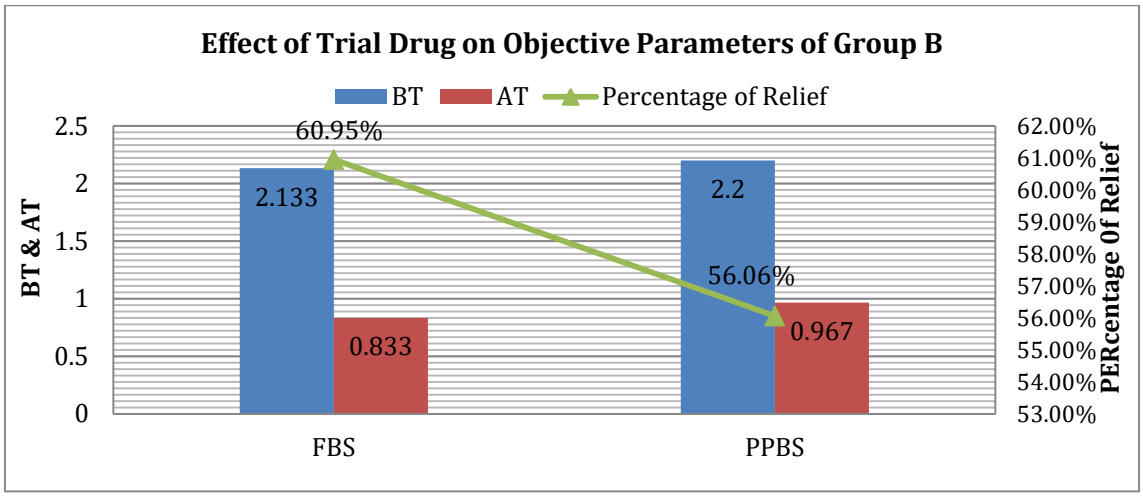
Subjective Parameters	n	Mean Score		MD	% of Relief	SD (±)	SE (±)	't' Value	'p' Value
		BT	AT						
Alasya	29	1.786	0.929	0.857	48%	1.145	0.217	3.95	<0.001
Karapada daha	19	1.474	0.842	0.632	42.88%	0.761	0.175	3.62	<0.01
PipasaAdhikya	17	1.706	1	0.706	41.38%	0.849	0.206	3.43	<0.01
Swedatipravritti	22	2.136	1.182	0.955	44.70%	1.09	0.232	4.1	<0.001
Shitapriyata	16	1.688	1	0.688	40.76%	0.704	0.176	3.9	<0.01
Madhuramasya	20	1.85	1.1	0.75	40.54%	0.911	0.204	3.68	<0.01
Swapnasukha	19	1.737	0.947	0.79	45.45%	0.918	0.211	3.74	<0.01



Graph 3: Effect of Trial Drug on Subjective Parameters of Group B

Table 10: Effect of Trial Drug on Objective Parameters of Group B Patients

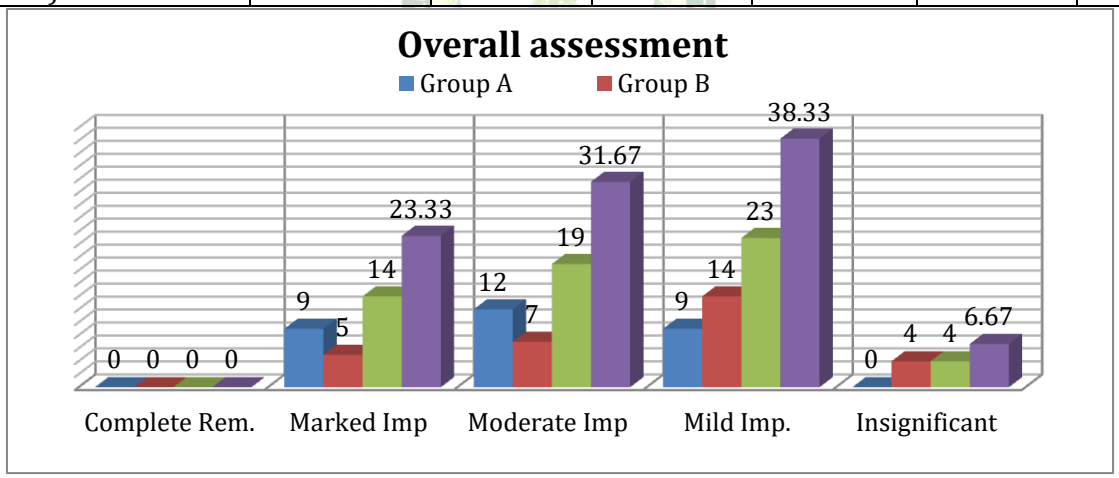
Objective Parameters	n	Mean Score		MD	% of Relief	SD (±)	SE (±)	't' Value	'p' Value
		BT	AT						
FBS	30	2.133	0.833	1.3	60.95%	1.442	0.263	4.94	<0.001
PPBS	30	2.2	0.967	1.233	56.06%	1.135	0.207	5.95	<0.001



Graph 4: Effect of Trial Drug on Objective Parameters of Group B

Table 10: Showing overall effect of treatment in 60 patients

Overall Effect	Group A (30 Patients)		Group B (30 Patients)		Total (60 Patients)	
	No. of Pts.	% of Pts.	No. of Pts.	% of Pts.	No. of Pts.	% of Pts.
Complete Remission (100% Relief)	0	0%	0	0%	0	0%
Marked Improvement (≥75% to < 100% relief)	09	30%	05	16.67%	14	23.33%
Moderate Improvement (≥50% to <75% relief)	12	40%	07	23.33%	19	31.67%
Mild Improvement (≥25% to <50% relief)	09	30%	14	46.67%	23	38.33%
Insignificant Result (<25% relief)	00	00%	04	13.33%	04	6.67%



Graph 5: Showing overall effect of treatment in 60 patients

DISCUSSION

For all clinical study, coherent interpretation and productive discussion is important, so that it contributes at least "squirrel service" to the remedial field, in turn serving the humanity. Here an attempt is made to discuss the concepts with respect to literary as well as on clinical work. The rapid increase in population, high ethnic susceptibility, rapid urbanization, the modern lifestyle with too much rich and refined food, too little exercise and stress most likely triggerd a Diabetes epidemic. The most disturbing trend in the shift in age of onset of prediabetes is to younger age in the recent years. This will have long lasting adverse effect on the nation's health and economy.

Beside the laboratory investigations an imaginary scoring protocol have been done for subjective and objective parameters, and scored by the condition nil (0), mild (1), moderate (2) and severe (3). The scoring points of BT and AT has been analyzed mathematically and statistically. The overall responses have been assessed by 5 categories, where insignificant response claimed by <25% relief, mild improvement claimed by ≥25% to <50% relief, moderate improvement claimed by ≥50% to <75%

relief, marked improvement claimed by ≥75% to < 100% relief and complete remission claimed by 100% relief.

In Group A, 30% of the patients achieved marked improvement, 40% of the patients achieved moderate improvement, and 30% of the patients achieved mild improvement. In Group B, 16.67% of the patients achieved marked improvement, 23.33% of the patients achieved moderate improvement, 46.67% of the patients achieved mild improvement and 13.33% having insignificant result. In summing up, it can be said that the present study showed significant remission in signs and symptoms of *Prameha* vis-à-vis Prediabetes corroborated with definite reduction in blood sugar levels. Therefore it is imperative that Powder *Kuberaksha* and Powder *Yava* helps in successful management of the disease and the drug *Kuberaksha* showed more significant result than the drug *Yava*.

CONCLUSION

In this study the broad term *Prameha* is correlated with Prediabetes and *Madhumeha* is correlated with Diabetes with its complications. Prediabetes is a condition where blood glucose level is higher than normal but not high enough to diagnosed as Diabetes. The chief complaints in this study are present in *Poorvarupa* of *Prameha*. These symptoms are almost same with the recently correlated prediabetes. Sedentary lifestyle, increased stress and strain, food habit, family history etc. are the main factors for the causation of Prediabetes. *Pathya* is the foundation stone for the treatment of prediabetes.

In *Alasya, Swedatipravritti* both drugs showed highly significant result where p<0.001 but the percentage of relief was more in case of *Kuberaksha*. In *Karapadadaha, Pipasadhikya, Shitapriyata, Madhuramasya* and *Swapnasukha* the drug showed highly significant result (p<0.001) and the drug Yava also showed significant results (p<0.01). Percentage of relief was more in Group A. In case of FBS and PPBS both drugs showed highly significant result i.e., p<0.001 and the percentage of relief was more in Group A (*Kuberaksha*). The study confirms that *Kuberaksha* and *Yava* are effective and safe in the treatment of prediabetes and definitely reduces the symptoms including FBS and PPBS. Treatment through *Kuberaksha* (*Caesalpinia bonduc*) was more effecting in combating prediabetes as compared to *Yava* (*Hordeum vulgare*). No adverse effects were observed during treatment. The present clinical study (Research work) may through a new light to the field in the management of Prediabetes and prevention of *Madhumeha* (Diabetes and its complication).

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