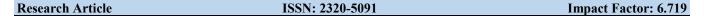


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A COMPARATIVE CLINICAL STUDY OF TWO VANGA BHASMA PREPARATIONS IN DIABETES MELLITUS (TYPE-II)

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ABSTRACT

The branch of *Ayurveda* which deals with the pharmaceutical preparation of *Rasaushdhis* is known as *Rasa-Shastra*. *Rasa-Chikitsa* was considered to be the most effective and time saving therapy. The preparations used under *Rasa-Chikitsa* being palatable, be preferred over other formulations for oral administration. Diabetes mellitus is a metabolic disorder caused due to relative or absolute deficiency of insulin, characterized mainly by hyperglycemia & poly urea. Lack of insulin affects the metabolism of carbohydrates, proteins and fat and also can cause significant disturbances in water and electrolytehomeostasis. In this present study two *yoga* of *Vanga* were taken as a trial drug one from the *Siddha Bhasajiya Mani Mala* and 2nd from *Rasayoga Sagar* both drug had *VangaBhasma* as main ingredient and in second drug *Haridra and Mocharasa* also as a main ingredient of the drug and all drug have the properties to overcome the effect of the diabetes. In this study we compared both the drug and made a clinical data of efficacy of the drugs. Clinically both the drugs showed effective results; among the two trial drugs *Vangayoga* 2 shows more results on FBS, PPBS and HBA1C in comparison to *Vangayoga* 1. *Vangayoga* 2 showed comparatively higher results in all subjective parameters except *trishnadhikya* then *Vangayoga* 1.

Keywords: Vanga Yoga, Siddha Bhasajiya Mani Mala, Rasayoga Sagar

INTRODUCTION

The branch of Ayurveda which deals with the pharmaceutical preparation of Rasaushdhis is known as Rasa-Shastra. Rasa-Chikitsa was considered to be the most effective and time saving therapy. The preparations used under Rasa-Chikitsa being palatable, be preferred over other formulations for oral administration¹. The present era is full of chaos, stress & strain due to lifestyle modifications, change in dietary habits, urbanization and industrialization. This has led in the upsurge of many diseases and one of them is diabetes mellitus. Prameha is a disease known since ancient time to the mankind and its upsurge is quiet alarming. Prameha is a metabolic disorder and is diagnosed mainly with the help of signs and symptoms related to 'Mutra' (Urine). Injudicious intake of food, sedentary lifestyle, stress, genetic predisposition is some of the important etiological factors of Prameha. According to Ayurveda text Vanga (Tin) Bhasma is having properties i.e. Balya, SarvaPramehanashaka, Kshayahara etc.² In this present study two yoga of Vanga were taken as a trial drug one from the Sidha Bhasajiya Mani Mala and 2nd from Rasayoga Sagar both drug had Vanga as main ingredient and in second drug Haridra (turmeric) and Mocharasa (Gum exudates of Salmalia malaberica) also as a main ingredient of the drug and all drug have the properties to overcome the effect of the diabetes. In this study we compared both the drug and made a clinical data of efficacy of the drugs. The present study was done in National Institute of Ayurveda, Jaipur.

Aim and Objectives

1. To provide patients safe and effective treatment and create a data of efficacy of the *Vanga* preparations.

Material and Methods:

Selection of Cases- The study was conducted on 30 clinically diagnosed Patients of *Madhumeha* (Diabetes Mellitus type II) and were taken from OPD and IPD of *Arogyashala* and Bombaywala hospital NIA, Jaipur.

Inclusion Criteria:

- 1. Patients between the ages 35 to 70 years of either sex irrespective of chronicity were taken.
- 2. Presence of sign and symptoms of *Madhumeha* described in *Ayurveda* classics.

- Confirmed cases of DM type II on the basis of laboratory investigations and observed sign and symptoms.
- Patients having hyperglycemia confirmed by laboratory investigations i.e. FBS≥126mg/dl or PPBS ≥200mg/dl
- 5. Glycosylated hemoglobin range ≥6%

Exclusion Criteria

- 1. Patient with type I Diabetes mellitus.
- 2. Patients who are insulin dependent.
- 3. Patients of Gestational Diabetes.
- 4. Patient having Type-II DM with any other serious systemic disease.
- 5. Nephropathy and other secondary complications
- Diabetes Mellitus produced due to other illnesses like Acromegaly, Cushing's syndrome, pancreatic disorders etc.

Administration of Drug-

30 clinically diagnosed patients were randomly divided into 2 Groups of 15 each as below:

- 1. **In first group** 15 patients were administered *Vanga* yoga I (*Siddha BheshajiyaMani Mala*) in the dose of 250 mg before meal two times a day with honey for 1 month.
- 2. **In second group** 15 patients were administered *Vanga* yoga II (*Rasayoga Sagar*) in the dose of 250 mg beforemeal two times a day with honey for 1 month.

Withdrawal Criteria

- 1. Patients developing any threatening complication during the trial.
- 2. Patient not willing to continue treatment.
- 3. Any other acute illness.

Informed consent: The purpose of the study, nature of the study drug and the potential risks and benefits were explained to the patients in detail in non-technical terms. There after their written consent was taken before starting the procedure.

Trial Drugs

- 1. Vanga Yoga I according to S.B.M.M (4/2-6PramehaChikitsa)
- 2. VangaYog II according to Rasayoga Sagar (Yoga No.-321Part-2ShalokNo. 1602)

Table D-1: Ingredients of *Vanga yoga* I according to S.B.M.M. (4/2-6prameha chikitsa³)

S.NO.	Ingredient	Botanical /English name	Part used	Quantity
1.	Haridra	Curcuma longa	Kanda	1 part
2.	Yavani	Trachyspermumammi	Fruit	1 part
3.	Lavang	Syzygiumaromaticum	Fruit	1 part
4.	Jira	Cuminum cyminum	Fruit	1 part
5.	Imali	Tamarandusindica	Bark	4 part
6.	Pippal	Ficus religiosa	Bark	4 part
7.	Apamarg	Achyranthus aspera	Panchang (whole plant)	4 part
8.	Vanga	Tin		2 part

For the study purpose *VangaBhasma* was prepared in the Department of Rasashastra and Bhaishajya Kalapana, National institute of Ayurveda, Jaipur. From raw *Vanga* metal, *Bhasma* was prepared by Shodhana (Purification)⁴, Jarana (assimilation of herbs in *Vanga* at a particular temperature in iron pan)⁵ and Marana (process of making *Bhasma* like incineration)⁶ processes with the method mentioned in *Rasa Ratna Samucchaya*, *Siddha Bhaishaja Mani Mala* and *Rasamrita* respectively.

Table D-2: Ingredients of Vanga yoga II according to Rasayoga Sagar (Yoga No.-321Part-2 Shalok No. 1602)⁷

Sr.no.	Ingredient	Name	Part use	Quantity
1.	Haridra	Curcuma longa	Kanda	1 part
2.	Mocha Rasa	Salmalia malabarica	Gum	1 part
3.	Vanga Bhasma	Tin		1 part

Bhasma of Vanga was prepared as per classical method and further all the ingredients mixed in equal quantity according to Rasayana Samgraha. (Rasayoga Sagar).

Dose & duration of clinical trial-

- 1. Dose- 250mg B.D. both of the preparations.
- 2. Duration—one month
- 3. Anupana- Madhu
- 4. Follow-up- Patients were followed up on 15th day of trial and after 1 month on completion of trial.

Design of the study:

- 1. Study type: Interventional
- 2. Intervention model: Two group assignment
- 3. Allocation: Randomized
- 4. Masking: Open label

- 5. Purpose: Treatment
- 6. Timing: 1 Month
- 7. End point: Efficacy
- 8. Subjects: 15 patients in each group.

Criteria for assessment:

- **1. Subjective Parameter-**The subjective parameters include for the assessment criteria.
- Prabhuta Mutrata.
- AavilMutrata.
- Atitrushna /Trishnadhikya
- Dourbalya,
- Kara-Pada-Tala daha.

1) Prabhuta Mutrata (Polyuria): Frequency of urine

Quantity of urine	Score
1.5 to 2.0 L / 24 hrs.	0
>2.0 to 2.5 L / 24 hrs	1
>2.5 to 3.0 L / 24 hrs	2
>3.00 L / 24 hrs.	3

Frequency of urine	Score
3 – 5 times per day, no or rarely at night	0
6-8 times per day, $1-2$ times per night	1
9 – 11 times per day, 3 – 4 times per night	2
> 11 times per day, > 4 times per night	3

2) Trishnadhikya (Polydipsia)

Symptom	Score
Feeling of thirst $7-9$ times/24 hours, either/or Intake of water $5-7$ times/24 hours with quantity	0
1.5 - 2.0 L/24 hours	
Feeling of thirst 9 - 11 times/24 hours, either/or Intake of water 7 - 9 times/24 hours with quantity	1
2.0 - 2.5 L/24 hours	
Feeling of thirst 11 – 13 times/24 hours, either/or Intake of water 9 – 11 times/24 hours with	2
quantity 2.50 -3.0L/24hours	
Feeling of thirst >13 times/24 hours, either/or Intake of water >11 times/24 hours with quantity	3
>3.0L/24 hours	

3) Avila Mutrata (Turbidity in urine)

Sp. Gravity- Score	Urine Sugar- Score	Albumin-Score	Total score of avilamutrata	Overall Score
1020-1025 - (0)	Nil (0)	Nil (0)	0	0
1026-1030 - (1)	+ (1)	+ (1)	1-3	1
1031-1035 - (2)	++ (2)	++ (2)	4-6	2
>1036 - (3)	+++ or more (3)	+++ or more (3)	7-9	3

4) Kara-Pada-Tala- Daha/ Supti (Burning sensation/ numbness in palm and soles)

Symptom	Score
No Daha	0
Kara-pada-tala-daha/Supti in continuous	1
Kara-pada-tala-daha/Supt icontinuous but not severe	2
Kara-pada-tala-daha/Supti continuous and severe	3

2. Objective Parameter-Blood Investigations

- C.B.C.
- Erythrocyte sedimentation rate (E.S.R) ir mm/hour.
- Fasting Blood Sugar (F.B.S) in mg/dl
- Post parandial Blood Sugar (P.P.B.S) in mg/dl
- Glycosylated hemoglobin

Urine Examination:

- Routine examination
- Microscopic examination

Routine Examination, Assessment and Follow up

Study: The full detailed history & physical

examination of patient was recorded as per the Proforma. Clinical & physiological assessment was done before treatment, in between trial on 15th day and after completion of treatment.

Duration of trial: 1 month **Results of Therapeutic Trial:**

In the present study 36 patients were registered out of which 30 completed the trial. The pattern of clinical improvement in two groups, both intra group wise and inter group wise were recorded and measured statistically in terms of various subjective, objective, and laboratory parameters.

Intra-Group Comparison

To assess the efficacy of treatment of each group, intra group wise comparison was done. As the variables of subjective parameters are non-parametric so, we used Wilcoxon matched-pairs signed-ranks test and other laboratory parameters are parametric thus we used **Paired student 't' test** for statistical analysis. The results are as follows:

Table R-1: Shows the pattern of clinical recovery in various 'Subjective Parameters' of *Madhumeha* diabetes mellitus in 15 patients treated *with* 'orally – 'Vanga Yoga I Group A' by Wilcoxon matched-pairs signed-ranks test.

S.	Symptoms	Mean		Diff.	% of	SD	SE	P	Results
No.		BT	AT		Relief				
1.	Prabhuta Mutrata	2.000	1.133	0.8667	43.335%	0.5164	0.1333	< 0.001	E.S.
2.	Frequency of urine	1.533	0.8667	0.6667	43.48%	0.6172	0.1594	< 0.01	V.S.
3.	Trishnadhikya	1.933	0.8667	1.067	55.19%	0.5936	0.1533	< 0.001	E.S.
4.	Avila Mutrata	2.133	1.067	1.067	50.02%	0.2582	0.06667	< 0.001	E.S.
5.	Daurabalya	2.067	1.133	0.9333	45.15%	0.5936	0.1533	< 0.001	E.S.
6.	Kara-pada-tala Daha	2.067	0.9333	1.133	54.81%	0.3519	0.09085	< 0.001	E.S.

Analysis of subjective parameters of Group A as per table R-1

Statistically extremely significant results (p<0.001) were found in *Prabhuta Mutrata*, *Trishnadhikya*,

Avila Mutrata, Daurabalya and Kara-pada-tala Daha.

➤ Statistically very significant result (p<0.01) was found in Frequency of urine.

Table R-2: Shows the pattern of clinical recovery in various 'Laboratory Investigations' of *Madhumeha* in 15 patients treated with "Vanga Yoga I" orally – 'Group A' by Paired 't' test.

S. No.	Variable	Mean		Dif.	% of	SD	SE	't'	P	Results
		BT	AT		Relief					
1.	TLC	8.653	8.887	-0.2333	2.69%	1.295	0.3345	0.6976	>0.05	N.S.
2.	Neutrophils	61.607	60.153	1.453	2.35%	3.436	0.8870	1.638	>0.05	N.S.
3.	Lymphocytes	32.253	33.007	-0.7533	2.33%	2.865	0.7396	1.019	>0.05	N.S.
4.	Eosinophils	3.053	3.440	-0.3867	12.66%	1.347	0.3479	1.111	< 0.01	V.S.
5.	Monocytes	3.747	3.087	0.6600	17.61%	2.362	0.6099	1.082	>0.05	N.S.
6.	Basophils	0.7200	0.2733	0.4467	62.04%	0.4673	0.1207	3.702	< 0.01	V.S.
7.	ESR	11.267	11.733	-0.4667	4.14%	3.441	0.8884	0.5253	>0.05	N.S.
8.	FBS	152.67	143.85	8.820	5.7%	17.824	4.602	0.0759	>0.05	N.S
9.	PPBS	197.26	163.77	33.493	16.97%	32.234	8.323	4.024	< 0.01	V.S.
10.	HbA ₁ C	7.880	7.273	0.6067	7.69%	0.5311	0.1371	4.424	< 0.001	E.S.
11.	specific gravity urine	1.027	1.031	-0.0042	0.4%	0.05369	0.0138	0.3030	>0.05	N.S.
12.	Serum cholesterol	183.22	181.05	2.167	1.18%	18.296	4.724	0.4587	>0.05	N.S.
13.	Serum glyceride	138.67	133.56	5.107	3.6%	12.470	3.220	1.586	>0.05	N.S.
14.	HDL	49.700	49.573	0.1267	.25%	3.995	1.031	0.1228	>0.05	N.S.

Analysis of Various Laboratory Parameters in Group A as per table R- 2.

- ➤ Statistically extremely significant results (p<0.001) was found in HBA1c.
- > Statistically very significant results(p<0.01) were found in eosinophils, basophil and PPBS.
- ➤ Statistically non-significant results (p>0.05) were found in all the other parameters.

Table R-3: Shows the pattern of clinical recovery in various 'Subjective Parameters' of *Madhumeha* /diabetes mellitus in 15 patients treated *with* 'orally – 'Vanga Yoga II Group B' by Wilcoxon matched-pairs signed-ranks test.

S. No.	Symptoms	Mean		Diff.	% of Relief	SD	SE	P	Results
		BT	AT						
1.	Prabhuta Mutrata	1.933	0.8667	1.067	55.19%	0.4577	0.1182	< 0.001	E.S.
2.	Frequency of urine	1.600	0.6667	0.9333	58.33%	0.5936	0.1533	< 0.001	E.S.
3.	Trishnadhikya	1.933	1.067	0.8667	44.83%	0.6399	0.1652	< 0.001	E.S.
4.	Avila Mutrata	2.133	1.067	1.067	50.02%	0.2582	0.06667	< 0.001	E.S.
5.	Daurabalya	2.333	1.267	1.067	45.73%	0.7037	0.1817	< 0.001	E.S.
6.	Kara-Pada-Tala	1.733	0.6667	1.067	61.56%	0.5936	0.1533	< 0.001	E.S.
	Daha								

Analysis of subjective parameters of Group B as per table R-3

> Statistically extremely significant results (p<0.001) were found in *Prabhuta Mutrata*, frequency of

urine, *Trishnadhikya*, *Avila Mutrata*, *Daurabalya* and *Kara-Pada-Tala Daha*.

Table R-4: Shows the pattern of clinical recovery in various 'Laboratory Investigations' of *Madhumeha* in 15 patients treated with "Vanga Yoga II" orally – 'Group B' by Paired 't' test.

S. No.	Variable	Mean		Dif.	% of	SD	SE	't'	P	Results
		BT	AT		Relief					
1.	TLC	8.793	8.747	0.04667	0.53%	1.054	0.2722	0.1715	>0.05	N.S.
2.	Neutrophils	57.547	57.667	-0.1200	0.20%	2.108	0.5443	0.2205	>0.05	N.S.
3.	Lymphocytes	34.753	35.167	-0.4133	1.18%	3.925	1.013	0.4079	>0.05	N.S.
4.	Eosinophils	2.907	2.440	0.4667	16.05%	1.071	0.2765	1.688	>0.05	N.S.
5.	Monocytes	3.920	3.187	0.7333	18.70%	2.134	0.5511	1.331	>0.05	N.S.
6.	Basophils	0.5600	0.2533	0.3067	54.76%	0.4758	0.1228	2.496	< 0.05	S.
7.	ESR	13.00	11.133	1.867	14.36%	3.482	0.8990	2.076	>0.05	N.S.
8.	FBS	170.58	149.54	21.040	12.33%	15.909	4.108	5.122	< 0.001	E.S
9.	PPBS	210.57	173.21	37.360	17.74%	37.647	9.720	3.843	< 0.01	V.S.
10.	HbA ₁ C	7.720	7.287	0.4333	5.6%	0.6466	0.1670	2.596	< 0.05	S.
11.	Urine specific gravity	1.021	1.027	-0.0062	0.60%	0.02945	0.0076	0.8241	>0.05	N.S.
12.	Serum cholesterol	196.59	187.71	8.880	4.5%	19.251	4.971	1.716	>0.05	N.S.
13.	Serum triglyceride	151.77	143.47	8.293	5.4%	18.718	4.833	1.716	>0.05	N.S.
14.	HDL	47.467	47.907	-0.4400	0.92%	3.821	0.9865	0.4460	>0.05	N.S.

Analysis of Various Laboratory Parameters in Group A as per table No. R- 4.

- ➤ Statistically extremely significant result (p<0.001) was found in FBS.
- ➤ Statistically very significant result (p<0.01) was found in PPBS.
- ➤ Statistically significant result (p<0.05) was found in HBA1C and Basophils.

Statistically non-significant results (p>0.05) were found in all the other parameters

Intergroup Comparison

To assess the comparative efficacy between two groups, intergroup comparison was done. As for the variables of subjective parameters are nonparametric, so we used Mann-Whitney test and other laboratory parameters are parametric thus we used Unpaired student 't' test for statistical analysis. The results are as follows:

Table R- 5: Showing Inter Group Comparison in Subjective Parameters by Mann Whitney Test

Symptoms	Group	Mean	S.D.±	S.E.±	P	Result
Prabhuta Mutrata	Grp A	0.8667	0.5164	0.1333	> 0.05	N.S.
	Grp B	1.067	0.4577	0.1182		
Frequency of urine	Grp A	0.667	0.6172	0.1594	> 0.05	N.S.
	Grp B	0.9333	0.5936	0.1533		
Trishnadhikya	Grp A	1.067	0.5936	0.1533	> 0.05	N.S.
	Grp B	0.8667	0.6399	0.1652		
Avila Mutrata	Grp A	1.067	0.2582	0.0667	> 0.05	N.S.
	Grp B	1.067	0.2582	0.0667		
Daurabalya	Grp A	0.9333	0.5936	0.1533	> 0.05	N.S.
	Grp B	1.067	0.7037	0.1817		
Kara-Pada-Tala	Grp A	1.133	0.3519	0.09085	>0.05	N.S.
Daha	Grp B	1.067	0.5936	0.1533		

Analysis of subjective parameters of Inter-Group Comparison as per table R-5: Statistically non-significant result (p>0.05) was found in all the subjective parameters

Table R-6: Showing Inter Group Comparison on 'Laboratory Investigations' of *Diabetes Mellitus* by Unpaired 't' Test:

Parameter	Group	Mean	S.D.	S.E.	"t"	P value	Significance
TLC	Group A	0.1593	1.269	-0.3276	0.5345	> 0.05	N.S.
	Group B	0.0667	1.036	0.2674			
Neutrophils	Group A	1.733	3.298	0.8515	1.695	> 0.05	N.S.
	Group B	0.0466	1.995	0.5152			
Lymphocytes	Group A	-0.6467	2.892	0.7468	1.854	> 0.05	N.S.
	Group B	-0.4133	3.925	1.013			
Eosinophils	Group A	-0.3867	1.347	0.3479	2.555	< 0.05	S.
	Group B	0.6933	0.9300	0.2401			
Monocytes	Group A	0.6600	2.362	0.6099	0.0892	> 0.05	N.S.
	Group B	0.7333	2.134	0.5511			
Basophils	Group A	0.4467	0.4673	0.1207	0.8130	> 0.05	N.S.
	Group B	0.367	0.4758	0.1228			
ESR	Group A	-0.4000	3.481	0.8987	1.783	> 0.05	N.S.
	Group B	1.867	3.482	0.8990			
FBS	Group A	9.060	17.807	4.598	1.943	> 0.05	N.S.
	Group B	21.040	15.909	4.108			
PPBS	Group A	32.827	32.634	8.426	0.2994	> 0.05	N.S.
	Group B	36.693	37.907	9.787			
Serum	Group A	2.167	18.296	4.724	1.388	> 0.05	N.S.
Cholesterol	Group B	15.480	32.328	8.347			
S. Tri-glyserides	Group A	5.133	12.506	3.229	0.5823	> 0.05	N.S.
	Group B	8.527	18.790	4.852			
H.D.L.	Group A	0.1933	4.035	1.042	0.05101	> 0.05	N.S.

		Group B	0.2667	3.838	0.9909			
Urine	specific	Group A	-0.00380	0.0537	0.0138	0.5972	> 0.05	N.S.
gravity		Group B	-0.01840	0.0779	0.02013			
HbA ₁ C		Group A	0.6267	0.5788	0.1494	0.8322	> 0.05	N.S.
		Group B	0.4400	0.6479	0.1673			

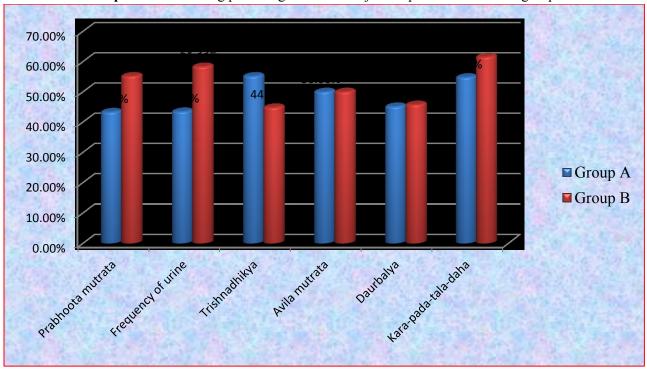
Analysis of Objective & laboratory Parameters of Inter-Group Comparison as per table no. R- 6

- > Statistically significant result (p<0.05) was found in Eiosinophil.
- Statistically non-significant result (p>0.05) was found in all the laboratory parameters.

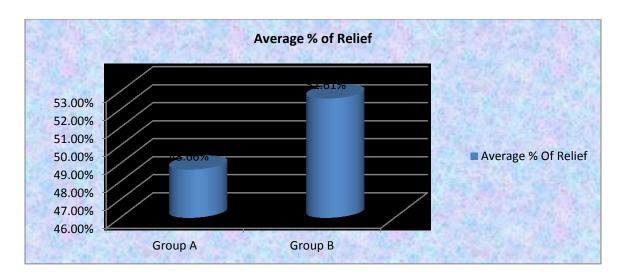
Table R-7: % Improvement of Subjective Parameters in Both Groups:

S.N.	Parameters	Result in Percentage				
		Group A (in %)	Group B (in %)			
1.	Prabhuta Mutrata	43.33%	55.19%			
2.	Frequency of urine	43.48%	58.33%			
3.	Trishnadhikya	55.19%	44.83%			
4.	Avila Mutrata	50.02%	50.02%			
5.	Daurbalya	45.15%	45.75%			
6.	Kara-Pada-Tala-Daha	54.81%	61.56%			
Average	% Of Relief	48.66%	52.61%			

Graph R-01: Showing percentage relief in subjective parameters in both groups



Graph R-02: Showing average percentage relief in subjective parameters in both groups



DISCUSSION OF RESULT

Intra-group comparison

- 1. Subjective parameters Interpretations: on subjective parameters both groups were showing almost equal effect only frequency of urine showed extremely significant result in group B, because in group A Vangayoga having only Vanga Bhasma but in B group VangaYoga having Mocharasa & Haridra choorna added thus it can be a effect of Kashaya Rasa, Stambhana Guna of Mocharasa and antidiabetic effect of Haridra.
- 2. **Objective parameters:** Group A showed extremely significant result in Hb1Ac, very significant in PPBS, Eosinophils and Basophils. Group B showed extremely significant result in FBS, very significant in PPBS, significant in Hb1Ac and basophils. Rest all other objective parameters showed non-significant result in both groups.

Inter-Group Comparison: In intergroup comparison both groups were having almost non-significant result only eosinophils having statistically significant result. Thus, statistically both groups were equally effective in treating *madhumeha*.

Average Percentage of relief: Comparing the symptomatic improvement in both groups it was found that average percentage of relief was a little bit higher in 'Group B' i.e. 52.61 %, followed by 'Group A' i.e. 48.66 %. It shows that effect of therapy was more in Group B than in comparison to Group A.

Clinically both the drugs showed effective results; among the two trial drugs *Vangayoga* 2 shows more results on FBS, PPBS and HBA1C in comparison to *Vangayoga* 1. *Vangayoga* 2 showed comparatively higher results in all subjective parameters except *trishnadhikya* then *Vangayoga* 1.

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CONCLUSION

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