



Research Article

ROLE OF *SOMVALK KASHAY ASTHAPAN BASTI* IN *PRAMEHA* W.S.R TO (DIABETES MELLITUS TYPE 2)

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ABSTRACT

The disease diabetes currently affects more than 62 million people which is more than 7.1% of India's adult population. The prevalence rate of diabetes in urban and rural areas is 10.3% and 6.2% respectively.

The Aim of the study is standardization of the method of preparation and administration of *Somvalk Kashay Asthapan Basti* and *Somvalk Siddha Taila Anuvasan Basti*. Two groups Group A (Trial Group) 50 patients is given *Somvalkkashayasthapan Basti*, and *Somvalk siddhataila anuvasanbasti* along with Metformin for 12 days and Group B (Control Group) 50 patients is given oral hypoglycemic drug and Metformin will be given according to the dosage 12 days.

Group A showed moderate improvement, while Group B showed no improvement. The overall result obtained in the present study shows 65% improvement in trial group which is moderate improvement according to the overall assessment criteria, whereas there was only 18% improvement in the control group which falls within unimproved category according to the overall assessment criteria.

The trial drug in the study i.e., *Somvalk kasha Asthapanbasti* has been proved significantly effective in symptoms like Polyuria, polydipsia, polyphagia and urine sugar. It has shown moderate effects on the symptoms like numbness and tingling. It has shown mild improvement in parameters of BSL- Fasting and BSL- PP.

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INTRODUCTION

The human race is very proudly holding its supreme position in this world. This supremacy comes partly as a gift from Mother Nature, but mostly due to the never ending efforts of the human. The modern world is full of examples of human intelligence and efforts. But the human has paid heavily for this advancement in the form of fast growing life style disorders. There is deterioration in the quality of life if seen from health point of view. In the race to gain supremacy and improved quality of life in the form of comforts, people have resorted to an unhealthy life style leading to stress, depression and various life style related disorders like obesity, heart disease and diabetes.

The theme for World health day 2016 was Diabetes. This itself emphasizes the importance, the WHO is giving to this disorder. As the prevalence of this disorder is increasing at a fast rate, it has become a concern for the health community.

Prevalence of the disease

According to the latest 2016 data from the WHO, about 422 million adults are living with diabetes mellitus. India would soon be the Diabetes capital of the world with a projected 109 million individuals with diabetes by 2035. This disease currently affects more than 62 million people which is more than 7.1% of India's adult population.³So, such is the picture of diabetes globally and in our

country. The prevalence rate of diabetes in urban and rural areas are 10.3% and 6.2% respectively. This indicates that the modern lifestyle is much responsible for the disease. The WHO defines diabetes as a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. There are two main types of diabetes. In type 1 diabetes, there is no insulin production in the body and therefore the patient requires insulin injections to survive. In Type 2 diabetes, which comprises 90% of the cases, patients are unable to use the insulin produced by the body. People with type 2 diabetes are typically overweight and are sedentary.

Though there have been many breathtaking advancements in the field of health and medicine, people are again turning towards the ancient ways of treatment and life style as there has been realization of the hazardous consequences of the fast and unhealthy life style. 'Ayurveda' is one such ancient 'science of life' which has proved its efficacy in solving many of the health problems related to unhealthy life style. This science of life which was originated in India, aims at keeping the healthy people healthy and treating the diseased people to enable them to lead long and healthy life.

Panchkarma is the branch which was till now considered adjuvant to *Kayachikitsa* but it has now emerged as a separate branch due to its importance in curing disease. *Panchkarma* which literally means 'five therapies' is a branch which deals with the *Shodhan* treatment. *Shodhan* means cleansing the body off its impurities. It has an upper edge on other types of treatments as *Shodhan* is *Apunarbhav* type of treatment, which means the diseases are eliminated along with its root cause thus, preventing its recurrence.

In Ayurveda, the disease called *Prameha* closely resembles diabetes mellitus. It has been described by nearly all the authors of ancient Indian medicine. The most popular description of *Prameha* is that given by Madhavnidan. The disease which is characterized by polyuria is known as *Prameha*. There are 20 types of *Prameha* described in the texts of Ayurveda by different Acharyas. These types are mainly based on the color of the urine passed by the person. A very detailed description of the etiology, pathology and treatment of *Prameha* is given by most of the Acharyas. A sedentary life style and wrong food habits (high carbohydrate intake) are considered as the main cause of *Prameha*.

Need of study: The present study is conducted to study the effect of '*Basti*' procedure of *Panchkarma*

which is the most effective modality of treatment for *Vaatdosha*. The drug used for *Basti* procedure is '*Somvalk*' which mainly acts upon *Kaphadosha*, and also has *Medoghna* property, *Meda* is the one of the *Dushyas* in *Prameha* and *Kapha* is the main *Dosha* involved in pathology of *Prameha*. Thus the combined effect of the drug and *Basti* therapy is expected to yield good results. The reference for the present study is taken from *Charaksamhita*, *Siddhisthan 10* i.e., '*Bastisiddhiadhyay*' in which Acharya Charak has described *Basti* medications according to various diseases. If this therapy is found adequately effective in controlling the blood sugar levels and the symptoms arising out of it, it can be used alone or in combination with the OHAs to give the diabetics relief from the daily painful pricks of insulin syringes. Moreover, it can be helpful in good control of blood sugar levels and can also reduce the dose of OHAs.

AIM AND OBJECTIVES

Aim

To study the role of *Somvalk Kashay Asthapan Basti* in *Prameha* W.S.R to (Diabetes mellitus Type 2).

Objectives

1. Literature review of *Somvalk Kashay Asthapan Basti* and Metformin in *Prameha* (Diabetes mellitus Type 2).
2. Standardization of the method of preparation and administration of *Somvalk Kashay Asthapan Basti* and *Somvalk Siddha Taila Anuvasan Basti*.
3. To observe if any adverse reaction occurs during the *Basti* process.

Materials and Methods

Materials needed for *Basti* procedure

1. *Tiltaila* for *Bahyasnehan* before *Basti*
2. *Nadiswedanyantra* for *Swedan*
3. Freshly prepared *Somvalk kwath*
4. *Somvalk siddha taila*
5. Enema apparatus
6. Glycerine syringe
7. Rubber catheter
8. Disposable glove

Method of Kwath (decoction) Preparation

The *Kwath* was prepared as per the procedure described by Sharangdhara. 1 *Pala Somvalk bharad* is mixed with 16 times water and it is reduced to 1/8th part to get the *Kwath*.

Somvalka kwath

Preparation of Asthapan Basti

There is a specific order of mixing various ingredients of *Niruha Basti* as described in *Ashtang Hruday*. First of all *Saindhav* was added to *Madhu* and mixed properly. Then *Tiltaila* was added and

mixed, followed by Kalka and finally the *Kwath* was added. The whole mixture was mixed thoroughly, and was heated to body temperature in a water bath.

Basti Dosage: For an adult person, the standard Basti dosage fixed by Charak is 12 *Prasruta*, which comes out to be 960 ml.

Sharangdhara has fixed *Bastimatra* as follows-

- *Uttammatra* - 80 Tola (800ml)
- *Madhyammatra*- 64 Tola (640ml)
- *Hinamatra* - 48 Tola (480ml)

In this study the *Madhyammatra* told by Sharangdhara was taken i.e., 640ml. This was done keeping in mind the practical difficulties faced by majority of patients in retaining large quantity of Basti fluid for a desirable period of time.

The quantity of *Sneha* in *Niruhabasti* in *Kaphapradhanvyadhi* is 1/8th of total *Bastidravya* quantity. So, the quantity of *Bastidravyas* was taken as follows.

- Kwath* - 5 parts = 400ml
- Sneha* -1.5 parts = 120ml
- Kalka* -1 part = 80gm
- Saindhav* = 10gm
- Madhu* = 30ml

Method of Preparation of Somvalk Siddha Taila

Somvalk siddhataila, used for *Anuvasan basti*, was prepared according to the following method. During the preparation of the *Taila*, *Somvalk* was used as *Kalkadravya*. The *kwath* used was also that of *Somvalk*, while *Tiltaila* was used as *Snehadravya*. The ingredients with their proportion used for the preparation of *Somvalk siddha taila* is as given below-

- Somvalk bharad* - 1 part
- Tilataila* - 4 parts
- Somvalk kwath* - 16 parts

Procedure

1. The *Kwath* was prepared according to reference of Sharangdhara as given above.
2. Now, the *Kwath* was mixed with the *Tiltaila* along with the *Somvalkkalka* in above mentioned proportion and subjected to heat.
3. This mixture was heated till the *Sneha siddhi lakshanas* were observed.

4. The *Somvalk siddha taila* thus prepared was then cooled and stored for further use.

Clinical Study: An open controlled clinical study was carried out. The patients were diagnosed on the basis of sign and symptoms of *Prameha* (Diabetes mellitus type 2) as per Ayurvedic and modern diagnostic methods.

Diagnosis was made with the help of following parameters-

Subjective parameters

- 1. Polyuria - *Prabhutmutrata*
- 2. Polydipsia - *Pipasaadhikya*
- 3. Poyphagia - *Kshudha*
- 4. Burning sensation- *Karpadadaha*
- 5. Polyneuritis - *Karapadasuptata*

Objective parameters

1. Blood sugar- Fasting 126mg/dl - 226mg/dl and Random 200mg/dl - 300mg/dl
2. Urine sugar - 0.05% and above.

Inclusion criteria

1. Age between 30-50 years.
2. Recently diagnosed cases (<1 year) of Diabetes mellitus Type II.
3. Patients with Fasting blood glucose 126mg/dl - 226mg/dl and PP blood glucose 200mg/dl - 300mg/dl
4. Patient taking Metformin (OHA) as regular treatment.

Exclusion criteria

1. Age below 30 and above 50 years.
2. *Jataha Prameha*.
3. Other associated complications like hypertension, any other CVS or CNS disorder.
4. Pregnant or lactating women.
5. Patients taking Insulin or any OHA other than Metformin as regular treatment.

Grouping of patients

Total diagnosed 100 no. of patients with consent were selected from the OPD and IPD of the college hospital.

Group A- Trial group

Group B- Control group

Group	Treatment	Duration
Group A (Trial Group) 50 patients	Somvalkkashayasthapan Basti, and <i>Somvalk siddha taila anuvasanbasti</i> along with Metformin	12 days
Group B (Control Group) 50 patients	Oral hypoglycemic drug, Metformin will be given according to the dosage	12 days

Drug administration details: The patients of Control Group were asked to continue to take their oral hypoglycemic drug Metformin in their prescribed dosage and schedule for a period of 12 days, after the initial diagnostic investigations.

The patients of Trial Group were administered *Somvalk kashay basti* and *Somvalk siddha anuvasan basti* along with their oral hypoglycemic drug Metformin in their prescribed dose and schedule for a period of 12 days, after the initial diagnostic investigations.

Administration of Basti

Asthapan basti of *Somvalk kwath* was administered. As per following reference

We cannot apply one type of *Basti* i.e. *Niruha* or *Anuvasana* continuously. If we apply *Anuvasana Basti* continuously it aggravates morbid matter and reduces the *Agni* i.e. digestive power and if we use *Niruha Basti* then it causes provocation of *Vata*. Thus *Niruha* after *Anuvasana* or vice versa are very much important to restore the body normalcy and to pacify the diseases.

So, *Somvalk siddha taila* was used for the *Anuvaasanbasti* which was given after 3 consecutive *Asthapan basti*.

Poorva karma

- Proper examination of the patient was carried out regarding the state of aggravated *Doshas*, *Agni*, *Bala*, *Satmya* etc.
- Blood pressure, pulse, respiration rate was recorded before the procedure.
- *Sthanikmriduabhyang* with *Tilataila* was done on *udar-kati-nitamb-jangha-jaanu-paad pradesh* of the patient.
- *Mridunadiswedan* was done on the *Abhyang* parts till the *Samyak swedan lakshanas* were observed.

Pradhan Karma: The *Niruhabasti* and *Anuvasan basti* were administered to the patients as per the schedule for 12 days.

- *Nirooha Basti- Somvalk kashaybasti* (640ml).
- *Anuvasan basti- Somvalk siddha taila* (60ml).

Sr. No	Treatment	Duration
1.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	1 st Day
2.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	2 nd Day
3.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	3 rd Day
4.	<i>Snehana and Mridu Swedanpurvak Anuvasan basti</i>	4 th Day
5.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	5 th Day
6.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	6 th Day
7.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	7 th Day
8.	<i>Snehana and Mridu Swedanpurvak Anuvasan basti</i>	8 th Day
9.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	9 th Day
10.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	10 th Day
11.	<i>Snehana and Mridu Swedanpurvak Niruhabasti</i>	11 th Day
12.	<i>Snehana and Mridu Swedanpurvak Anuvasan basti</i>	12 th Day

- Ideally, *Anuvasan basti* should be retained for 12hrs.
- And *Niruhabasti* should be retained for 48 minutes.
- It is then allowed to come out along with fecal matter and excess *Pitta* and *Kapha*.
- The patients were instructed to evacuate bowel when there is urge of passing stools. Patients were instructed not to strain or pass motion forcibly or retain forcibly.

Paschaat karma

Anuvasan basti- *Sphikatadana*, *Shayaya Utkshepana*-3 times.

Niruhabasti: Supine position was given to the patient and pillow was placed below the lower back region.

Advice given after the procedure

- 1) To take hot water bath after *Basti Pratyagamana*.
 - *Anuvasana Bastipratyagamanakaal*- 3 *Yama*
 - *Niruhabastipratyagamanakaal* - 1 *Muhurta*
- 2) To take normal diet, but less in quantity and avoid spicy food.
- 3) To avoid heavy work, walking, running, day sleep, exercise etc.

After the administration of *Basti*, the observations were recorded in the *Basti* record

chart every day. The data thus collected was then subjected to statistical analysis at the end of the clinical trial.

Following symptom score will be adopted for the assessment.

- 0- Completely relieved
- 1- Mild symptoms present
- 2- Moderate symptoms present
- 3- Severe symptoms present

Polyuria (*Prabhutmootrata*)

Score	Frequency of urine
0	Frequency of 4-6 times/24 hrs
1	Frequency of 7-9 times/24 hrs
2	Frequency of 10-12 times/24 hrs
3	Frequency of > 13 times/24 hrs

Polydipsia (*Pipasaadhikya*)

Score	Assessment criteria
0	Absent (taking 8-10 glass of water/day)
1	Taking 10-15 glass of water/day
2	Taking 15-20 glass of water/day
3	Unable to have sound sleep due to thirst

Polyphagia (*Kshudhaadhikya*)

Score	Assessment Criteria
0	2 Chapati/meal
1	3-4 Chapati/meal
2	4-5 Chapati/meal
3	>5 Chapati/meal

Burning sensation of soles and palms (*Karapadadaha*)

Score	Assessment Criteria
0	Absent
1	Occasional
2	Continuous
3	Continuous and require medication

Polyneuritis (*Karapadasuptata*)

Score	Assessment Criteria
0	Absent
1	Occasional
2	Continuous
3	Continuous and require medication

Observations and Result

Table 1: Distribution according to Age

Groups		Group A		Group B		Total	
Sr.No.	Age	Count	Percent	Count	Percent	Count	Percent
1	30 - 34	4	8.00%	5	10.00%	9	9.00%
2	35 - 39	13	26.00%	13	26.00%	26	26.00%
3	40 - 44	12	24.00%	15	30.00%	27	27.00%

Groups		Group A		Group B		Total	
Sr.No.	Age	Count	Percent	Count	Percent	Count	Percent
4	45 - 50	21	42.00%	17	34.00%	38	38.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 4 patients (8%) were having age between 30 - 34 years, 13 patients (26%) belonged to age group 35 - 39 years, 12 patients (24%) were having age between 40 - 44 while 21 patients (42%) belong to age group 45 - 50 years.

In group B, 5 patients (10%) were having age between 30 - 34 years, 13 patients (26%) belonged to age group 35 - 39 years, 15 patients (30%) were having age between 40 - 44 while 17 patients (34%) belong to age group 45 - 50 years.

Table 2: Distribution according to Gender

Groups		Group A		Group B		Total	
Sr.No.	Gender	Count	Percent	Count	Percent	Count	Percent
1	Male	27	54.00%	30	60.00%	57	57.00%
2	Female	23	46.00%	20	40.00%	43	43.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 27 patients (54%) were male while 23 patients (46%) were female. While in group B, 30 patients (60%) were male while 20 patients (40%) were female.

Table 3: Distribution according to Religion

Groups		Group A		Group B		Total	
Sr.No.	Religion	Count	Percent	Count	Percent	Count	Percent
1	Hindu	48	96.00%	48	96.00%	96	96.00%
2	Muslim	2	4.00%	2	4.00%	4	4.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 48 patients (96%) were Hindu while 2 patients (4%) were Muslim. Whereas in group B too, 48 patients (96%) were Hindu while 2 patients (4%) were Muslim.

Table 4: Distribution according to Habitat

Groups		Group A		Group B		Total	
Sr.No.	Diet	Count	Percent	Count	Percent	Count	Percent
1	Rural	42	84.00%	44	88.00%	86	86.00%
2	Urban	8	16.00%	6	12.00%	14	14.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 42 patients (84%) were from rural area while 8 patients (16%) were from urban area. Whereas, in group B, 44 patients (88%) were from rural area while 6 patients (12%) were from urban.

Table 5: Distribution according to Diet

Groups		Group A		Group B		Total	
Sr.No.	Diet	Count	Percent	Count	Percent	Count	Percent
1	Mixed	47	94.00%	44	88.00%	91	91.00%
2	Vegetarian	3	6.00%	6	12.00%	9	9.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 47 patients (94%) were having mixed diet while 3 patients (6%) were vegetarian. Whereas, in group B, 44 patients (88%) were having mixed diet while 6 patients (12%) were vegetarian.

Table 6: Distribution according to Nature of work

Groups		Group A		Group B		Total	
Sr.No.	Nature of work	Count	Percent	Count	Percent	Count	Percent
1	Heavy	5	10.00%	9	18.00%	14	14.00%
2	Medium	19	38.00%	18	36.00%	37	37.00%
3	Sedentary	26	52.00%	23	46.00%	49	49.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 5 patients (10%) were doing heavy work, 19 patients (38%) were concerned with medium strenuous work while 26 patients (52%) were having sedentary nature of work. In group B, 9 patients (18%) were doing heavy work, 18 patients (36%) were concerned with medium strenuous work while 23 patients (46%) were having sedentary nature of work.

Table no: 7 Prakruti wise distribution

Groups		Group A		Group B		Total	
Sr.No.	Prakruti	Count	Percent	Count	Percent	Count	Percent
1	Vata - Pitta	5	10.00%	8	16.00%	13	13.00%
2	Vata - Kapha	10	20.00%	8	16.00%	18	18.00%
3	Pitta - Vata	3	6.00%	0	0.00%	3	3.00%
4	Pitta - Kapha	9	18.00%	10	20.00%	19	19.00%
5	Kapha - Vata	10	20.00%	10	20.00%	20	20.00%
6	Kapha - Pitta	13	26.00%	14	28.00%	27	27.00%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 5 patients (10%) were of Vata - Pitta prakruti, 10 patients (20%) were from Vata - Kaphaprakruti, 3 patients (6%) were from Pitta - Vata prakruti, 9 patients (18%) were from Pitta - Kaphaprakruti, 10 patients (20%) were of Kapha - Vata prakruti while 13 patients (27%) were of Kapha - Pitta prakruti.

In group B, 8 patients (16%) were of Vata - Pitta prakruti, 8 patients (16%) were from Vata - Kaphaprakruti, 10 patients (20%) were from Pitta - Kaphaprakruti, 10 patients (20%) were of Kapha - Vata prakruti while 14 patients (28%) were of Kapha - Pitta prakruti.

Table 8: Socio-economic status

Groups		Group A		Group B		Total	
Sr.No.	Class	Count	Percent	Count	Percent	Count	Percent
1	High	37	74%	32	64%	69	69%
2	Middle	9	18%	10	20%	19	19%
3	Low	4	8%	8	16%	12	12%
Total		50	100.00%	50	100.00%	100	100.00%

In group A, 37 patients (74%) belonged to higher class, 9 patients (18%) belonged to middle class, while 4 patients (8%) belonged to lower class. In group B, 32 patients (64%) belonged to higher class, 19 patients (20%) belonged to middle class, while 8 patients (16%) belonged to lower class.

Statistical analysis of different parameters: As grading used for some assessment parameters were ordinal in nature, "Wilcoxon Signed Rank test" is used for intra-group comparison. (i.e. before and after treatment of a group) while for inter-group comparison, (i.e. for comparing two groups with each other) "Mann-Whitney U test" is used. For quantitative parameters, intra group comparison is done with "paired t test" while for inter-group comparison, "Unpaired t test" is used.

We have tested hypothesis for each parameter and result is interpreted accordingly. The level of significance is kept at 0.05. Proper summary statistics like mean, median, S.D., IQR (Inter Quartile Range) are provided along with graphical and diagrams.

Table 9: Prabhootmootrata (Polyuria)

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	2.54	0.30	2.24	2.00	1.0 (3.0 - 2.0)	50	1275.00	< 0.001
Group B	2.36	1.68	0.68	0.50	1.0 (1.0 - 0.0)	50	340.50	< 0.001

For group A, the median reduction in *Prabhutmootrata* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in *Prabhutmootrata* for Group A. For group B, the median reduction in *Prabhutmootrata* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. in group B too, there is significant reduction in *Prabhutmootrata*.

Table 10: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2.00	2.24	0.66	2241.00	< 0.001
Group B	0.50	0.68	0.91		

Reduction in *Prabhutmootrata* score for group A was significantly higher than that in group B (p -value < 0.001) at 5% level of significance. Thus, **treatment A can be considered as more effective in reducing *Prabhutmootrata* as compared to treatment B.**

Table 11: Gradation wise distribution of patients

<i>Prabhutmootrata</i>		0		1		2		3	
		No.	%	No.	%	No.	%	No.	%
Group A	BT	0	0.00%	1	2.00%	21	42.00%	28	56.00%
	AT	36	72.00%	13	26.00%	1	2.00%	0	0.00%
Group B	BT	0	0.00%	3	6.00%	26	52.00%	21	42.00%
	AT	6	12.00%	7	14.00%	34	68.00%	3	6.00%

Table 12: Pipaasaadhikya (Polydipsia)

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	2.34	0.42	1.92	2.00	0.0 (2.0 - 2.0)	50	1275.00	< 0.001
Group B	2.24	1.70	0.54	0.00	1.0 (1.0 - 0.0)	50	231.00	< 0.001

For group A, the median reduction in *Pipaasaadhikya* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in *Pipaasaadhikya* for Group A. For group B, the median reduction in *Pipaasaadhikya* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. in group B too, there is significant reduction in *Pipaasaadhikya*.

Table 13: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2.00	1.92	0.53	2274.50	< 0.001
Group B	0.00	0.54	0.76		

Reduction in *Pipaasaadhikya* score for group A was significantly higher than that in group B (p -value < 0.001) at 5% level of significance. Thus, treatment A can be considered as more effective in reducing *Pipaasaadhikya* as compared to treatment B.

Table 14: Gradation wise distribution of patients

<i>Pipaasaadhikya</i>		0		1		2		3	
		No.	%	No.	%	No.	%	No	%
Group A	BT	0	0.00%	1	2.00%	31	62.00%	18	36.00%
	AT	32	64.00%	15	30.00%	3	6.00%	0	0.00%
Group B	BT	0	0.00%	3	6.00%	32	64.00%	15	30.00%
	AT	5	10.00%	6	12.00%	38	76.00%	1	2.00%

Table 15: Kshudhaadhikya (Polyphagia)

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	1.57	0.24	1.33	1.00	1.0 (2.0 - 1.0)	49	1225.00	< 0.001
Group B	1.92	1.44	0.48	0.00	1.0 (1.0 - 0.0)	48	171.00	< 0.001

For group A, the median reduction in *Kshudhaadhikya* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e., it can be said that there is significant reduction in *Kshudhaadhikya* for Group A. For group B, the median reduction in *Kshudhaadhikya* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e., in group B too, there is significant reduction in *Kshudhaadhikya*.

Table no: 16: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	1.00	1.33	0.47	1949.00	< 0.001
Group B	0.00	0.48	0.71		

Reduction in *Kshudhaadhikya* score for group A was significantly higher than that in group B (p -value < 0.001)at 5% level of significance. Thus, treatment A can be considered as more effective in reducing *Kshudhaadhikya* as compared to treatment B.

Table 17: Gradation wise distribution of patients

<i>Kshudhaadhikya</i>		0		1		2		3	
		No.	%	No.	%	No.	%	No	%
Group A	BT	1	2.00%	25	50.00%	20	40.00%	4	8.00%
	AT	38	76.00%	12	24.00%	0	0.00%	0	0.00%
Group B	BT	2	4.00%	15	30.00%	22	44.00%	11	22.00%
	AT	10	20.00%	15	30.00%	21	42.00%	4	8.00%

Table 18: Kara-paaduptata (Numbness)

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	1.69	0.43	1.27	1.00	1.0 (2.0 - 1.0)	49	1176.00	< 0.001
Group B	1.75	1.33	0.42	0.00	1.0 (1.0 - 0.0)	48	210.00	< 0.001

For group A, the median reduction in *suptata* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in *Suptata* for Group A. For group B, the median reduction in *Suptata* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. in group B too, there is significant reduction in *Suptata*.

Table 19: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	1.00	1.27	0.53	1968.00	< 0.001
Group B	0.00	0.42	0.50		

Reduction in *Suptata* score for group A was significantly higher than that in group B (p -value < 0.001) at 5% level of significance. Thus, treatment A can be considered as more effective in reducing *Suptata* as compared to treatment B.

Table 20: Gradation wise distribution of patients

Suptata		0		1		2		3	
		No.	%	No.	%	No.	%	No	%
Group A	BT	1	2.00%	22	44.00%	20	40.00%	7	14.00%
	AT	30	60.00%	19	38.00%	1	2.00%	0	0.00%
Group B	BT	2	4.00%	23	46.00%	14	28.00%	11	22.00%
	AT	8	16.00%	26	52.00%	10	20.00%	6	12.00%

Table 21: Kara-paaddaha (Burning sensation of palms and soles)

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	1.62	0.44	1.19	1.00	1.0 (2.0 - 1.0)	48	990.00	< 0.001
Group B	1.71	1.41	0.31	0.00	1.0 (1.0 - 0.0)	49	120.00	< 0.001

For group A, the median reduction in *Daha* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e., it can be said that there is significant reduction in *Daha* for Group A. For group B, the median reduction in *Daha* score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. in group B too, there is significant reduction in *Daha*.

Table 22: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	1.00	1.19	0.57	1991.50	< 0.001
Group B	0.00	0.31	0.47		

Reduction in *Daha* score for group A was significantly higher than that in group B (p -value < 0.001) at 5% level of significance. Thus, treatment A can be considered as more effective in reducing *Daha* as compared to treatment B.

Table 23: Gradation wise distribution of patients

Kara-paad Daha		0		1		2		3	
		No.	%	No.	%	No.	%	No	%
Group A	BT	2	4.00%	23	46.00%	20	40.00%	5	10.00%
	AT	29	58.00%	21	42.00%	0	0.00%	0	0.00%
Group B	BT	1	2.00%	24	48.00%	15	30.00%	10	20.00%
	AT	6	12.00%	25	50.00%	13	26.00%	6	12.00%

Table 24: Urine sugar

Group	Mean score			Median diff.	IQR of diff. Q ₃ - Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
	B.T	A.T	diff					
Group A	2.16	0.40	1.76	2.00	1.0 (2.0 - 1.0)	50	1275.00	< 0.001
Group B	2.22	1.76	0.46	0.00	1.0 (1.0 - 0.0)	50	276.00	< 0.001

For group A, the median reduction in Urine sugar score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. it can be said that there is significant reduction in Urine sugar for Group A. For group B, the median reduction in Urine sugar score after treatment is significant (P-value < 0.001) at 5% level of significance. i.e. in group B too, there is significant reduction in Urine sugar.

Table 25: Comparative Analysis of Groups

Group	Median difference (bef-aft)	Mean of difference (bef-aft)	S.D. of difference (bef-aft)	Mann-Whitney U statistic	P- Value
Group A	2.00	1.76	0.59	2316.00	< 0.001
Group B	0.00	0.46	0.50		

Reduction in urine sugar score for group A was significantly higher than that in group B (p -value < 0.001) at 5% level of significance. Thus, treatment A can be considered as more effective in reducing urine sugar as compared to treatment B.

Table 26: Gradation wise distribution of patients

Urine sugar		0		1		2		3	
		No.	%	No.	%	No.	%	No	%
Group A	BT	0	0.00%	5	10.00%	32	64.00%	13	26.00%
	AT	30	60.00%	20	40.00%	0	0.00%	0	0.00%
Group B	BT	0	0.00%	2	4.00%	35	70.00%	13	26.00%
	AT	0	0.00%	14	28.00%	34	68.00%	2	4.00%

Fasting Blood Sugar Level

Table 27: Decrease in Fasting Blood Sugar Level (Group A)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Fasting Blood Sugar Level	184.80	159.74	25.06	50	16.45	2.33	10.77	< 0.001

Using paired t test, for Fasting Blood Sugar Level, p - value is less than 0.001 i.e. the difference between mean Fasting Blood Sugar Level before and after treatment is significant at 5% level of significance. i.e. we can say that There is decrease in Fasting Blood Sugar Level for group A.

Table 28: Decrease in Fasting Blood Sugar Level (Group B)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Fasting Blood Sugar Level	179.16	172.28	6.88	50	15.56	2.20	3.13	0.001

Using paired t test, for Fasting Blood Sugar Level, p - value is less than 0.001 i.e. the difference between mean Fasting Blood Sugar Level before and after treatment is significant at 5% level of significance. i.e. we can say that There is decrease in Fasting Blood Sugar Level for group B.

Table 29: Comparative analysis of groups

Group	Mean difference	S.D. of difference	n	d.f.	Two sample "t"	P- value
Group A	25.06	16.45	50	98	8.739	< 0.001
Group B	6.88	15.56	50			

The mean decrease in Fasting Blood Sugar Level for group A and mean decrease of group B was significantly different (P-value < 0.001) at 5% level of significance. Thus treatment A can be considered as more effective in decreasing Fasting Blood Sugar Level as compared to treatment B.

Post-prandial Blood Sugar Level

Table 30: Decrease in Post-prandial Blood Sugar Level (Group A)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Post-prandial Blood Sugar Level	262.84	227.02	35.82	50	17.29	2.45	14.65	< 0.001

Using paired t test, for Post-prandial Blood Sugar Level, p - value is less than 0.001 i.e. the difference between mean Post-prandial Blood Sugar Level before and after treatment is significant at 5% level of significance. i.e. we can say that There is decrease in Post-prandial Blood Sugar Level for group A.

Table 31: Decrease in Post-prandial Blood Sugar Level (Group B)

Parameter	Mean Score			n	SD	SE (±)	Paired "t"	"p-value" (One tailed)
	B.T.	A.T	Diff.					
Post-prandial Blood Sugar Level	244.00	232.12	11.88	50	12.86	1.82	6.53	< 0.001

Using paired t test, for Post-prandial Blood Sugar Level, p - value is less than 0.001 i.e. the difference between mean Post-prandial Blood Sugar Level before and after treatment is significant at 5% level of significance. i.e. we can say that There is decrease in Post-prandial Blood Sugar Level for group B.

Table 32: Comparative analysis of groups

Group	Mean difference	S.D. of difference	n	d.f.	Two sample "t"	P- value
Group A	35.82	17.29	50	98	7.86	< 0.001
Group B	11.88	12.86	50			

The mean decrease in Post-prandial Blood Sugar Level for group A and mean decrease of group B was significantly different (P-value < 0.001) at 5% level of significance. Thus treatment A can be considered as more effective in decreasing Post-prandial Blood Sugar Level as compared to treatment B.

Table 33: Comparative efficacy

Parameter	Group A	Group B	Comparative efficacy
Polyuria	Significant	Significant	Group A
Polydipsia	Significant	Significant	Group A
Polyphagia	Significant	Significant	Group A
Numbness	Significant	Significant	Group A
Tingling	Significant	Significant	Group A
Urine sugar	Significant	Significant	Group A
BSL – fasting	Significant	Significant	Group A
BSL – PP	Significant	Significant	Group A

Table 34: comparison of improvement in both Groups

Parameter	Mean % improvement	
	Group A	Group B
Polyuria	88.67%	24.33%
Polydipsia	84.33%	22.00%
Polyphagia	89.12%	25.69%
Numbness	79.93%	25.35%
Tingling	75.69%	19.05%
Urine sugar	83.00%	19.33%
BSL - fasting	13.21%	03.54%
BSL - PP	13.56%	04.71%
Overall Mean % improvement	65.94%	18.00%

Overall Effect of Therapy

While assessing overall efficacy of treatments, all assessment parameters were used. The criteria for assessment are as below.

Table 36: Distribution of patients according to relief

Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Marked improvement	10	20.00%	00	00.00%
Moderate improvement	37	74.00%	00	00.00%
Mild improvement	03	06.00%	12	24.00%
Unimproved	00	00.00%	38	76.00%
Total	50	100.00%	50	100.00%

In group A, 10 patients (20%) were observed with marked improvement, 37 patients (74%) were moderately improved while 3 were (6%) seen with mild improvement.

In group B, 12 patients (24%) realized mild improvement while 38 patients (76%) were not improved.

DISCUSSION

In order to draw appropriate conclusion, it becomes inevitable to ponder over each fact and observation obtained from the study. This is achieved by the section of discussion over every aspect of the disease, the treatment and the observations. It will also help in better analysis and understanding of the subject. So, a discussion will be done in following three sections-

Conceptual discussion

Prameha is the disease of *Tridosha* predominance and *Bahudrava Shlesma* is the main element. *Vata* is the originator and executor of the all the functions of the body. The *Vyanavayu* is responsible for effective transport and circulation of all *Bhavaib* the body. *Apanavayu* is related to the functions of *Pakvasaya* and *Basti* and is responsible to hold and excrete the waste at proper time. In *Prameha* both types get vitiated leading to the

abnormal pathway and excessive elimination respectively. *Shlesma* is basis for the structural integrity of the body and it provides sturdiness and strength in the body.

All these function of *Shlesma* get hampered in the *Prameha*, due to increase of *Dravaguna* of *Shleshma*. When *Kapha* get vitiated it undoubtedly vitiates the body elements like *Rasa*, *Mamsa*, *Meda*, *Vasa*, *Lasika*, *Oja*.

Pitta dosha, is mainly related with the digestion and metabolism. In case of *Prameha*, due to etiological factors, *Pitta* also get vitiated it and in turn affect the normal functions of *Jathragni* and *Dhatwagni* leading to the excessive formation of deranged quality *Rasa*, *Mamsa*, *Meda* etc. This in turn leads to the *Dhatushaithilya* and production of *kleda*.

Thus in *Prameha* because of the above pathophysiological processes they i.e. *Dusya*

obstructs the normal pathway of *Vata* causing *Avaran* to it that in turns aggravate the *Vyana* leads to the transport of vital *Dhatu Oja* towards *Basti* where already aggravated *Apana* excretes out it from the body resulting depletion of *Dhatu*s and generate disease *Prameha*. This pathogenesis mainly described by Charaka. Excess of deranged *Shlesma*, *Meda*, *Kleda*, *Vasa*, *Lasika* etc. aggravated *vata* produces various pathophysiological changes in the body producing symptoms like *Prabhata-mutrata*, *Avilamutra*, *Pipasa*, *Daurbalya*, *Alasaya* etc. leads to the structural as well as functional abnormalities in the body.

Acharya Sushruta specifically mentioned that in *Prameha* the vitiated *Doshas* remains situated in the lower part of the body owing to the inefficiency of various *Dhamanis* i.e. vessels (Su.Chi. 12/8). The *Doshas* should be eliminated through the nearest path.

Mode of action of drug: According to Ayurveda, *Samprapti Vighatana* is the main basis for the treatment of every disease. In *Prameha*, the vitiated *Kapha* and *Pitta* obstructs the path of *Vata*, causing its vitiation. Thus, the treatment should involve drugs that are effective in combating the 'Drava' guna of *Shleshma*, which is the first cause of the starting of the *Samprapti*. So, drug having *Ruksha*, *Tikshna*, *Ushna* properties would be of great use. Such drugs will also help in reduction of the excessive *Kleda*, which leads to *Dhatushaithilya*.

The drug *Somvalk*, selected for the trial is having *Tikta*, *Kasaya*, *Rasa Usna Veerya* and *Laghu*, *Ruksa Guna*, *Katu Vipaka* and *Kaphavatahara* properties.

Even the *Avaapdravyas* used in the *Basti* preparation possess the same qualities and help in enhancing its action. Thus, *Usna Veerya* and *Tikta Kasaya Rasa* help to normalize the function of *Jathragni* and *Dhatwagni*. That in turn helps to form the *Dhatu*s in proper proportion with *Samyak* qualities.

Laghu Ruksa Guna helps for the *Sosan* of *Bahudrava Shlesma* and reduction of vitiated *Meda Kleda*.

Thus once these factors get normalized in the body they in turn clear the Path of *Vata* which stops the depletion of vital *Dhatu*s and restore normal physiology.

Moreover, *Somvalka* is included in *Mootra Sangrahaniyagana* by Acharya Charaka. This also acts on the *Mootravahastrotas* and helps in reducing the symptoms like *Prabhutmootrata* and *Avilmootrata*.

Mode of action of Basti: *Basti* is useful not only in disorders of *Vaata*, but also for *Pitta*, *kapha* and *Rakta*. It is also useful in *Samsarga* and *sannipatajvyadhis*. (su.chi 35/3) Similarly, *Basti* works according to its *Veerya*. So, use of *Ushnaviryya* drugs in the *Basti*, makes the *Basti* itself *Ushnaviryatmaka*. *Niruhabasti* also acts as a *Shodhan* procedure (*Doshanirharan*), so it also qualifies as per the line of treatment of *Prameha* which states that first *Shodhan* should be undertaken in treating the *Prameha*. As *Niruhabasti* is better than *Vaman* or *Virechan* due to less complication, it seems to be the perfect choice for the treatment.

Basti is proven to be effective to eliminate out the metabolic waste. It increases the *Agni* power. It also helps to normalise the function of *Rasavaha*, *Medovaha*, *Mutravaha Srotasa*. *Basti* drugs after absorption also helps to perform the *Samprapti Vighatana*, as they possess *Pramehaghna* quality. *Anuvasana* also due to *Kasaya* present in it acts against *Meda* and *Kapha* while *Sneha* helps to normalize the *Vata*.

Thus *Basti* is helpful to reduce the excess of *Kleda*, purifies every channel, normalizes the function of *Apana* and *Vyana* and proves beneficial in *Prameha*.

Discussion on Clinical trial: An open controlled clinical study was carried out. The total 100 number of patients diagnosed on the basis of inclusion criteria were divided into two groups.

Group A- Trial group, 50 patients of trial group were administered *Somvalkkashaybasti* and *Somvalk siddha anuvasanbasti* along with their oral hypoglycemic drug *Metformin* in their prescribed dose and schedule for a period of 12 days.

Group B- Control group, 50 patients of Control Group were asked to continue to take their oral hypoglycemic drug *Metformin* in their prescribed dosage and schedule for a period of 12 days.

Follow up was taken on 13th day. The observations as made during the study, were subjected to suitable statistical tests for better analysis and for obtaining the result.

General observations

Age: It was observed from the present study that most of the patients (38%) of *Prameha* belonged to the age group of 45-50 years. The age group of 30-34 years was the least affected group. This was observed because of in this age, there is natural aggravation of *Vatadosha*, which is the main factor in causation of any disease.

Sex: It was observed from the present study that maximum number of patients were males in both the groups. This is mainly due to demographic situation pertaining to this region.

Religion: Most of the patients were Hindus (96%), while 4% patients were Muslims. This is also due to more number of Hindu residents in the study region.

Habitat: Maximum patients were from rural area (86%). Remaining (14%) were from urban area. This is because the study has been conducted in rural area, so maximum number of patients were from rural habitat.

Diet: Maximum patients were taking mixed diet (91%), while remaining were vegetarian. Excessive intake of nutritious diet is a prominent factor in *Prameha*.

Nature of work: Most of the patients were having sedentary nature of work (49%). Least number of patients (14%) were involved in heavy work. Since most of the people lead modern life style which involves use of all types of comforts in home as well as at their place of work, this leads to over nutrition and occurrence of diseases.

Prakruti: Maximum patients were *Kapha-pittaj* (27%) and *Kapha-vatajprakruti* (20%). Least patients were of *Vaat-pittaj* (3%) *Prakruti*. This indicates that the disease occurrence is more in *Kapha* dominant *Prakrutis*.

Socioeconomic status: Maximum patients belonged to higher class (69%). Least number of patients belonged to lower class (12%). High socioeconomic status enables earning of all sorts of comforts and thus contributes in sedentary life, which is the cause of *Prameha*.

Discussion of assessment parameters

Polyuria: In group A, the mean score before treatment was 2.54 which reduced to 0.30 after treatment.

In group B, the mean score before treatment was 2.36 which reduced to 1.68 after treatment.

The difference in mean score before and after treatment observed in group A was 2.24, whereas in group B it was only 1.68.

Thus, the result in Group A was more significant than Group B.

The significant result in group A, indicates that the *Somvalkkashay Basti* acts on the *Mootravahastrotas*, it also is able to reduce the *Kleda*.

Polydipsia: In group A, the mean score before treatment was 2.34 which reduced to 0.42 after treatment.

In group B, the mean score before treatment was 2.24 which reduced to 1.70 after treatment. The difference in mean score before and after treatment observed in group A was 1.92, whereas in group B it was only 0.54.

Thus, the result in Group A was more significant than Group B.

The decrease in polydipsia is probably due to decrease in polyuria, as the hydration is maintained due to less frequency of passing urine.

Polyphagia: In group A, the mean score before treatment was 1.57 which reduced to 0.24 after treatment.

In group B, the mean score before treatment was 1.92 which reduced to 1.44 after treatment. The difference in mean score before and after treatment observed in group A was 1.33, whereas in group B it was only 0.48.

Thus, the result in Group A was more significant than Group B.

The reduction in *Dhatuagnimandya* leads to the formation of good quality of *Dhatu*s and thereby proper nutrition of body, so as nutrition can be achieved within the limited amount of food, there is reduction in the demand of food by the body. The decrease in polyphagia indicates correction of *Jatharagni* of the patients. It is also the *Lakshana* of *Samyak yoga* of *Basti* therapy.

Kar-paaduptata (Polyneuritis): In group A, the mean score before treatment was 1.69 which reduced to 0.43 after treatment. In group B, the mean score before treatment was 1.75 which reduced to 1.33 after treatment. The difference in mean score before and after treatment observed in group A was 1.27, whereas in group B it was only 0.42.

Thus, the result in Group A was more significant than Group B.

Suptata is the symptom of vitiated *Kapha* and after the treatment, the *Kaphashamak* action of the *Somvalk* helps to reduce this symptom of *Suptata*.

Kara-paaddaha (burning sensation of palms and soles)

In group A, the mean score before treatment was 1.62 which reduced to 0.44 after treatment. In group B, the mean score before treatment was 1.71 which reduced to 1.41 after treatment. The difference in mean score before and after treatment observed in group A was 1.19, whereas in group B it was only 0.31.

Thus, the result in Group A was more significant than Group B.

Urine sugar: In group A, the mean score before treatment was 2.16 which reduced to 0.40 after treatment. In group B, the mean score before treatment was 2.22 which reduced to 1.76 after treatment. The difference in mean score before and after treatment observed in group A was 1.76, whereas in group B it was only 0.46.

Thus, the result in Group A was more significant than Group B.

The reduction in urine sugar is due to reduction in the blood sugar level.

Fasting Blood Sugar Level: In group A, the mean score before treatment was 184.80 which reduced to 159.74 after treatment. In group B, the mean score before treatment was 179.16 which reduced to 172.28 after treatment. The difference in mean score before and after treatment observed in group A was 25.06, whereas in group B it was only 6.88.

Thus, the result in Group A was more significant than Group B.

Post Prandial Blood Sugar Level: In group A, the mean score before treatment was 262.84 which reduced to 227.02 after treatment. In group B, the mean score before treatment was 244 which reduced to 232.12 after treatment. The difference in mean score before and after treatment observed in group A was 35.82, whereas in group B it was only 11.88.

Thus, the result in Group A was more significant than Group B.

The reduction in fasting and post prandial blood sugar levels is due to the correction of *Dhatvagni* i.e., correction in metabolism of the food taken.

Total effect of the therapy

Polyuria: The mean percentage of improvement in group A was 88.67% as compared to 24.33% in group B.

Polydipsia: The mean percentage of improvement in group A was 84.33% as compared to 22% in group B.

Polyphagia: The mean percentage of improvement in group A was 89.12% as compared to 25.69% in group B.

Kara-paadsuptata (Numbness): The mean percentage of improvement in group A was 79.93% as compared to 25.35% in group B.

Kara-paaddaha (burning sensation of palms and soles): The mean percentage of improvement in group A was 75.69% as compared to 19.05% in group B.

Urine sugar: The mean percentage of improvement in group A was 83% as compared to 19.33% in group B.

BSL-Fasting: The mean percentage of improvement in group A was 13.21% as compared to 03.54% in group B.

BSL- PP: The mean percentage of improvement in group A was 13.56% as compared to 04.71% in group B.

Overall Effect of Therapy

Distribution of patients according to relief: In Group A, 20% of patients showed marked improvement; the highest 74% showed moderate improvement; 6% of patients showed mild improvement while, none were left unimproved. In Group B, none of the patients showed marked or moderate improvement, 24% of the patients showed mild improvement and most of the patients i.e., 76% showed no improvement. So, it can be concluded from above that Group A showed moderate improvement, while Group B showed no improvement. The overall result obtained in the present study shows 65% improvement in Trial group which is moderate improvement according to the overall assessment criteria, whereas there was only 18% improvement in the Control group which falls within unimproved category according to the overall assessment criteria. The unimproved condition in the Control group was recorded, as the patients of this group were taking the OHA Metformin according to their need and as per their prescription. The little variation which was observed in the Control group is negligible and can be attributed to variation within the normal range. The moderate improvement in the Trial group indicates that, apart from the effects of OHA, the Basti therapy also had a positive impact on the signs and symptoms of the patients, which is reflected in the much higher result in Trial group as compared to the control group. This can be justified because, there was an no intervention as such in the Group B, while the *Basti* therapy showed its add-on effect in the patients of Group A.

CONCLUSION

The trial drug in the study i.e., *Somvalk kasha Asthapanbasti* has proved significantly effective in symptoms like Polyuria, polydipsia, polyphagia and urine sugar. It has shown moderate effects on the symptoms like numbness and tingling. It has shown mild improvement in parameters of BSL- Fasting and BSL- PP

The '*Somvalk kashay asthapan basti*' can be used as adjuvant therapy along with, diet control and exercise as first line of treatment. It can be

useful as a preventive measure in case of pre diabetics after further research on pre diabetics.

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