



E-ISSN: 2321-2187
P-ISSN: 2394-0514
IJHM 2017; 5(5): 78-82
Received: 11-07-2017
Accepted: 12-08-2017

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A comparative clinical evaluation of *Vang Bhasma* with *Shuddha Shilajatu* and *Vang Bhasma* with *Guduchi Satva* in the management of *Prameha* with special reference to diabetes mellitus

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Abstract

Prameha is a common disease encountered by clinicians in daily practice. It is mainly characterized by polyuria and turbid urine. A number of formulations are described in *Ayurvedic* literature for management of *Prameha*. To establish a reliable therapeutic module, a clinical trial was carried out to evaluate therapeutic efficacy of *Vang Bhasma* with *Shuddha Shilajatu* and *Vang Bhasma* with *Guduchi Satva* in relief in symptoms of *Prameha* and also to compare the effect of both drugs. It was open randomized comparative clinical study with pre and posttest design. 20 patients were diagnosed as suffering from *Prameha*. These patients were randomly divided into 2 groups of 10 patients each. 10 patients were treated with *Vang Bhasma* with *Shuddha Shilajatu* and 10 patients were treated with *Vang Bhasma* with *Guduchi Satva* for 30 days. They were evaluated on subjective parameters like *Prabhuta mutrata*, *Pipasa*, *Kshudha*, *Klama*, *Karapada daha*, *Karapada suptata*, *Pindikio udveshtana*, *Mukha shosha* and *Sandhi shoola*. Fasting and Post prandial blood sugar level of each patient was also observed. There was marked relief in symptoms of *Prameha* in patients of both groups as evidenced by reduction in the mean score of various subjective parameters and laboratory investigations. There was statistically highly significant result in most of the subjective parameters, but while comparing both the groups, there was insignificant difference in the results. Thus it can be stated that *Vang Bhasma* with *Shuddha Shilajatu* and *Vang Bhasma* with *Guduchi Satva* both therapeutic modules are effective in relieving symptoms of *Prameha* as evidenced by statistically significant reduction in the symptom score of various subjective and objective parameters.

Keywords: *Vang Bhasma*, *Shuddha Shilajatu* *Guduchi Satva*, *Prameha*, Fasting blood sugar

1. Introduction

Diseases are like curse to the healthy life and manifest themselves as a hindrance in leading a happy and prosperous living. Day to day stress at work and at home adds to the hostile environment against good health. In this pursuit, it has always been felt useful to explore the *Ayurvedic* resources to prevent and control many diseases and also life style.

Prameha is described as *Mahagada* ^[1] in *Ayurvedic* literature characterized by *Prabhuta avila mutrata* ^[2] (polyuria and turbid urine). The associated symptoms like *Gaurava*, *Baddhata*, *Jadya*, *Akasmata mutra nirgama*, *Kshudhadhikya*, *Daurbalya*, *Aalasya* and *Swedadhikya* ^[3] etc. are also found in this condition. As per modern concept, it can be correlated with Diabetes mellitus. It comprises a group of metabolic disorders that share common phenotype of hyperglycemia ^[4]. It is the key risk factor for most of the life threatening non communicable diseases like hypertension and cardio vascular disease etc.

Diabetes mellitus has emerged as a global health hazard having tremendous socio-economic impact to the individual as well as society as a whole. In spite of tremendous advances in modern medical sciences, today Diabetes is the most common non-communicable disease (NCD). According to International Diabetic Federation (IDF), in the year 2014, worldwide about 387 million people were afflicted with diabetes, the majority of which were aged between 40-59 years, and 80% of them live in low and middle income countries ^[5].

Since synthetic drugs like oral hypoglycemic agents and Insulin have been shown to have side effect, clinical importance of metallic and herbal drugs in the treatment of Diabetes mellitus has received considerable attention in recent years. The metallic drug *Vang Bhasma* ^[6], mineral drug *Shuddha Shilajatu* ^[7] and herbal drug *Guduchi Satva* ^[8] are described as *Prameha hara* i.e. Anti-diabetic drugs in *Ayurvedic* classics. Hence the proposed study was undertaken to evaluate and establish the *Prameha hara* effect of *Vang Bhasma* with *Shuddha Shilajatu* and *Vang Bhasma* with *Guduchi Satva*.

2. Materials and Methods

It was an open clinical trial with randomized sampling. The trial drugs *Vang Bhasma*, *Shuddha Shilajatu* and *Guduchi Satva* were selected on the basis of classical references as well as modern knowledge of drugs. *Vang Bhasma* is calcinated form of *Vang* (Tin) while *Shuddha Shilajatu* is purified form of Black Betumin (*Asphaltum punjabinum*) and *Guduchi Satva* is solid extract of *Guduchi* (*Tinospora cordifolia*).

2.1 Ethical clearance: The proposed clinical study was presented in form of synopsis in front of Institutional Ethical Committee (IEC) of Rajiv Gandhi Govt. P.G. Ayurvedic College, Paprola, Distt. Kangra, Himachal Pradesh. The clinical trial was started after getting the approval from the Secretary of IEC vide letter no. IEC/2014/665 dated 25-05-2014.

2.2 Method of collection of data: A special perform was prepared incorporating demographic data of patients, detailed clinical history and all the clinical manifestation and assessment criteria of *Prameha* including laboratory investigations.

2.3 Selection of patients: 20 patients were selected for this study from O.P.D. of Department of *Ras Shastra* and *Bhaishajya Kalpana*, Rajiv Gandhi Govt. P.G. Ayurvedic College and Hospital, Paprola, Distt. Kangra, H.P. irrespective of their sex, religion and socio economic status. A written and informed consent of patients was taken before trial.

2.4 Inclusion criteria

- Patients willing for clinical trial and ready to give written consent.
- Patients in the age group of 30 – 60 years of either sex.
- Patients possessing signs and symptoms of *Prameha* (Diabetes Mellitus).
- Patients having Fasting blood sugar > 126 mg/dl and Post prandial blood sugar > 200 mg/dl.

2.5 Exclusion criteria

- Patients not willing for the clinical trial.
- Patients not fulfilling the inclusion criteria.
- Patients below the age of 30 years and above the age of 60 years.
- Patients of Insulin dependent Diabetes mellitus (IDDM).
- Patients complicated with any cardiac problem.
- Diabetes due to endocrinopathies.
- Drug or chemical induced Diabetes mellitus.
- Patients suffering from AIDS, Cancer, TB or any other severe systemic disorders.

2.6 Laboratory investigations: Fasting blood sugar and Post prandial blood.

2.7 Intervention: A total number of 20 patients willing for the trial and fulfilling the criteria for selection were selected for this study. They were randomly divided into two groups-

- **Group-I:** 10 patients were registered in Group- I, in which 7 patients completed the trial and 3 patients left the treatment. These patients were treated with Cap. *Vang Bhasma* in the dose of 125 mg twice a day and Cap. *Shuddha Shilajatu* in the dose of 500 mg twice a day with lukewarm water. The duration of trial was 30 days.

- **Group-II:** 10 patients were registered in Group- II, in which 8 patients completed the trial and 2 patients left the treatment. These patients were treated with Cap. *Vang Bhasma* in the dose of 125 mg twice a day and Cap. *Guduchi Satva* in the dose of 500 mg twice a day with lukewarm water. The duration of trial was 30 days.

2.8 Criteria for assessment: To observe the effect of therapy, the patients were thoroughly assessed for improvement in subjective and objective criteria before and after the therapy on the basis of grading and scoring system. These criteria are-

- **Subjective criteria:** *Prabhuta mutrata* (polyuria), *Pipasa* (polydipsia), *Kshudha* (polyphagia), *Klama* (fatigue), *Karapada daha* (burning hands and feet), *Karapada suptata* (numbness), *Pindiko udveshtana* (calf tenderness), *Mukha shosha* (dryness of mouth) and *Sandhi shoola* (joint pain) [9].
- **Objective criteria:** Fasting blood sugar > 126 mg/dl and Post prandial blood sugar > 200 mg/dl [10].

2.9 Statistical analysis: The scores of criteria of assessment were analyzed statistically in the form of Mean, Standard Deviation (\pm SD) and Standard Error (\pm SE). Student's Paired 't' test was applied to observe the significance of results. The results obtained were interpreted as Table 1.

Table 1: Interpretation of statistical values

'p' Value	Result
$p > 0.05$	Insignificant
$p < 0.05$	Significant
$p < 0.01$	Significant
$p < 0.001$	Highly significant

3. Observations

Among 20 patients registered for the clinical study, 50% patients were in the age group of 40-50 years, 60% patients were female and all the patients were Hindu. All the patients in this study were married. Maximum patients i.e. 80% reside in rural area. On considering education, 45% patients were metric educated. In this study, 50% patients were housewives followed by 35% patients were in Govt. job, 55% patients had mild physical activity. Most of the patients i.e. 55% belonged to middle class category of society, 70% patients were having increased appetite, 90% patients were addicted to tea, 70% patients were having regular bowel habit and 85% patients had increased micturation pattern. In this study, 50% patients were of *Vata Kaphaja Prakriti* followed by 30% patients of *Pitta Kaphaja Prakriti*. 55% patients were having onset of disease for less than one year duration followed by 25% patients between 1-5 years. 60% patients had no family history of *Prameha* while 40% patients presented with positive family history of the disease. Among various signs and symptoms, *Prabhuta mutrata*, *Pipasa*, *Kshudha*, *Klama*, *Pindiko udveshtana* and was observed in all the twenty (100%) patients, *Karapada daha* and *Sandhi shoola* was observed in eighteen (90%) patients, *Mukha shosha* was observed in fifteen (75%) patients.

4. Results

4.1 Group- I: The present study reveals that there was 73.24% improvement in *Pipasa*, 75.44% improvement in *Klama*, 72.13% improvement in *Karapada daha*, 67.03% improvement in *Pindiko udveshtana* and 73.25%

improvement in *Sandhi shoola*. These results were highly significant with $p < 0.001$. On the other hand, there was 68.07% improvement in *Prabhuta mutrata*, 70.42% improvement in *Kshudha*, 76% improvement in *Karapada suptata* and 74.38% improvement in *Mukha shosha*. These results were significant with $p < 0.01$. The percentage relief in Fasting blood sugar and Post prandial blood sugar was 31.42% and 33.43% respectively. These results were insignificant with $p > 0.05$. [Table 2]

4.2 Group- II: In Group- II, there was 58.33% improvement

in *Kshudha*, 58.35% improvement in *Karapada suptata* and 68.56% improvement in *Mukha shosha*. These results were highly significant with $p < 0.001$. On the other hand, there was 57.14% improvement in *Prabhuta mutrata*, 50% improvement in *Pipasa*, 57.40% improvement in *Klama*, 63.63% improvement in *Karapada daha*, 61.53% improvement in *Pindiko udveshtana* and 60% improvement in *Sandhi shoola*. These results were significant with $p < 0.01$. The percentage relief in Fasting blood sugar and Post prandial blood sugar was 22.47% and 27.74% respectively. These results were insignificant with $p > 0.05$. [Table 2]

Table 2: Effect of therapy on both groups

Parameters	Group- I				Group- II			
	Mean Score		% relief	p value	Mean Score		% relief	p value
	BT	AT			BT	AT		
Subjective Parameters								
<i>Prabhuta mutrata</i>	1.66	0.53	68.07%	<0.01	1.75	0.75	57.14%	<0.01
<i>Pipasa</i>	1.57	0.42	73.24%	<0.001	1.50	0.75	50.00%	<0.01
<i>Kshudha</i>	1.42	0.42	70.42%	<0.01	1.50	0.62	58.33%	<0.001
<i>Klama</i>	1.71	0.42	75.44%	<0.001	1.75	0.75	57.40%	<0.01
<i>Karpada daha</i>	1.83	0.51	72.13%	<0.001	1.37	0.50	63.63%	<0.01
<i>Karpada suptata</i>	1.50	0.36	76.00%	<0.01	2.00	0.83	58.35%	<0.001
<i>Pindiko udveshtana</i>	1.85	0.61	67.03%	<0.001	1.62	0.62	61.53%	<0.01
<i>Mukha shosha</i>	1.60	0.41	74.38%	<0.01	1.25	0.37	68.56%	<0.001
<i>Sandhi Shoola</i>	1.57	0.42	73.25%	<0.001	1.25	0.50	60.00%	<0.01
Laboratory Investigations								
Fasting Blood Sugar	185.67	127.32	31.42%	>0.05	169.71	131.57	22.47%	>0.05
Post prandial Blood Sugar	294.68	196.16	33.43%	>0.05	281.56	203.43	27.74%	>0.05

4.3 Inter-group comparison: It shows that there was no statistically significant difference in the effect of therapy on all the cardinal symptoms with $p > 0.05$. Although percentage relief in the cardinal symptoms was more in Group- I

(72.22%) than that in Group- II (59.44%). The percentage relief in Fasting blood sugar and Post prandial blood sugar was also more in Group- I than that in Group- II. [Table 3]

Table 3: Inter group comparison of therapy

Parameters	% Relief		% Difference	p value
	Group- I	Group- II		
Subjective Parameters				
<i>Prabhuta mutrata</i>	68.07%	57.14%	10.93%	>0.05
<i>Pipasa</i>	73.24%	50.00%	23.24%	>0.05
<i>Kshudha</i>	70.42%	58.33%	12.09%	>0.05
<i>Klama</i>	75.44%	57.40%	18.04%	>0.05
<i>Karpada daha</i>	72.13%	63.63%	08.50%	>0.05
<i>Karpada suptata</i>	76.00%	58.35%	17.65%	>0.05
<i>Pindiko udveshtana</i>	67.03%	61.53%	05.50%	>0.05
<i>Mukha shosha</i>	74.38%	68.56%	05.82%	>0.05
<i>Sandhi Shoola</i>	73.25%	60.00%	13.25%	>0.05
Laboratory Investigations				
Fasting Blood Sugar	31.42%	22.47%	08.95%	>0.05
Post prandial Blood Sugar	37.40%	30.69%	06.71%	>0.05

4.4 Overall effect of the therapy: Among 7 patients of Group- I, 2 patients (28.57%) were moderately improved while 5 patients (71.43%) were highly improved. In Group-

II, 4 patients (50%) were moderately improved while 4 patients (50%) were highly improved. [Table 4]

Table 4: Overall effect of therapy

Effect	Group- I		Group- II	
	No. of patients	percentage	No. of patients	percentage
No Improvement	0	0%	0	0%
Mild Improvement	0	0%	0	0%
Moderate Improvement	2	28.57%	4	50%
Highly Improvement	5	71.43%	4	50%
Complete Remission	0	0%	0	0%

5. Discussion

This clinical study was conducted to evaluate the efficacy of *Vang Bhasma* with *Shuddha Shilajatu* and *Vang Bhasma* with *Guduchi Satva* in the relief in symptoms of *Prameha* and also to compare the effect of both drugs. The outcome of the study showed ample evidence in regard to action of these drugs. These drugs were prepared in Charak Govt. Ayurvedic Pharmacy, Paprola, Distt. Kangra, Himachal Pradesh.

5.1 Probable mode of action of *Vang Bhasma*: In *Vanga Bhasma*, *Tikta*, *Katu Rasa*, *Laghu*, *Ruksha Guna*, *Ushna Virya* and *Katu Vipaka* ^[11] might have corrected the *Kapha Dushti*. Along with this, it contains *Tikta Rasa*, which might have corrected the vitiation of *Pitta* and also helpful in channelizing vitiated *Rasa dhatu*. Due to its *Ushna Virya*, it breaks the *Aavarana* of *Vata*. This *Tridosha shamaka* property of drug helped to correct the *Dhatu dushti* and *Sroto dushti* leading to their normal functioning. The *Ushna Virya* with *Deepana* property may have attributed in *Amapachana* by stimulating *Jatharagni* ^[12], which is also one of the prime etiological factors. Again these properties act at the level of *Dhatwagni* facilitating the metabolism. Once metabolism control is achieved, the pathological changes like mylenopahty which occur mostly due to metabolic dysfunction, gets rectified. The pharmacological action like *Medohara* and *Lekhana* ^[11] may be helpful in reducing *Bahu* and *abadha Meda* and facilitating circulation and normal binding of insulin.

5.2 Probable mode of action of *Shuddha Shilajatu*: *Tikta Rasa*, *Ushna Virya* and *Katu Vipaka* of *Shilajatu* ^[13] will have acted upon the *Kapha Dushti*. *Ushna Virya* breaks *Aavarana* of *Vata* and normalise the *Dhatvaagni* along with *Amapachana* which facilitates the normal metabolism in the body ^[12]. *Tikta* and *Kashaya Rasa* helped in *Pitta shamna*. In *Prameha*, body acquires *Shaithilya* due to *Bahu* and *abadha Kapha* and *Meda* ^[14]. *Shilajatu*, having *Deha dardhyakara* property ^[15], enables to improve the consistency and quality of tissue elements. *Meda* and *Kapha* are the main etiological factors in the obstruction of the *Srotas* and causes *Srotodushti*. *Medo-chedana* property of *Shilajatu* ^[16] initiates removal of excess *Meda* and expelled the vitiated material from the *Srotas*. Lysis of excess *Meda* also helps in rectifying the insulin receptors which may be helpful in proper utilization of glucose by target cells. *Shilajatu* possess *Tridosha shamak* properties ^[17]. As in *Prameha*, *Tridosha* are involved, it normalizes all the *Doshas*. *Shilajatu* also have *Rasayan* property ^[18], which not only corrects the hyperglycemic episodes, but also produce their effect by enhancing the *Agni* and *Ojas* status, thereby an improved metabolic and immune status of the patient.

5.3 Probable mode of action of *Guduchi Satva*: *Kashaya* and *Tikta Rasa* of *Guduchi* ^[19] balances vitiated *Kapha* and *Pitta*. *Ushna Virya* ^[19] breaks *Aavarana* of *Vata* and also corrects *Kapha dushti*. *Dahashamak* ^[20] properties of *Guduchi* helps in relieving symptoms like *Mukha shosha* and *Karapada daha*. *Guduchi* also possess *Tridosha shamaka* ^[19] properties. So it normalizes all the *Doshas* and relieves the disease. *Rasayana* property ^[21] of *Guduchi* helps in improving metabolic and immune status of the patient by enhancing the *Agni* and *Ojas* Also imparts immune power and rejuvenation to the body. These properties of *Guduchi Satva* helps in effectively counteract the etiopathogenesis of *Prameha*.

6. Conclusion

In the present study, both drugs were effective in relieving signs and symptoms of *Prameha* and also possess significant effect in lowering the fasting and post-prandial blood sugar level. Although there was statistically significant relief in both the groups, yet *Vang Bhasma* with *Shuddha Shilajatu* in Group- I showed better relief in symptoms without any statistically significant difference. No adverse effect was noted during the treatment and follow up period in both the groups. However this is only a preliminary study conducted as a part of educational research program with small number of patients for a short duration of time, further multi-centric, clinical and experimental studies are required with larger sample size to establish *Prameha hara* (anti-diabetic) effect of these drugs.

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