

A STUDY ON EFFICACY OF SUDDHA SHILAJEET IN VATIK PRAMEHA UPADRAVA

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ABSTRACT

Prameha is a disease of whole urinary tract. The meaning of Prameha is passing out of turbid urine in excessive amount. Prameha is included under Astamahagada because of its co-morbidity and dreadful complications. Prameha is a Tridoshaja Vyadhi where 10 dushyas are involved. Due to 'Ansana-Kaplana' of dosha and dushya several types of prameha are found. Different gunas of doshas combined with dushyas to produce specific types of Prameha. Among the 20 types of prameha, vatic prameha is incurable. In Vatik prameha dhatu kshay occurs rapidly which leads to serious complications. All types of prameha is converted to Madhumeha due to dhatu kshay and pitta or kapha avrita vayu. This ultimately leads to Ojah kshay and formation of Upadrava. So in Vatik prameha, Santarpana chikitsa is advisable. In the present study a clinical trial was conducted on 35 patients in order to prove the efficacy of Shilajeet in Vatik Prameha Upadrava. Dose was Suddha Shilajeet capsule 500 mg twice daily before food for 60 days with 1 cup of milk. After completion of treatment significant improvement was found in different signs and symptoms.

Keywords: Vatik prameha, Upadrava, Shilajeet, Santarpana chikitsa

"Shilajeet" or "Silajatu" comprises of two terms, one 'Sila' and other 'Jatu'.

INTRODUCTION

Prameha has been known to the Indian system of medicine since Vedic period. Prameha is described as kulaja (familial) roga [1]. The disease along with all of its causes, aetiopathogenesis, symptomatology, treatment and complication is mentioned in all Ayurvedic texts penned centuries ago. Its inclusion in eight major diseases (Maharoga) indicates the significance and gravity attributed to it [2]. Due to lack of proper defense mechanism, chronicity of the disease some unwanted symptom/syndrome appears in the body, in case of almost all diseases and particularly in metabolic disorder. This leads to further aggravation in discomfort which can be termed as complication of the disease. It can be diminished by increasing awareness about the disease as well as by providing right treatment at right time. Upadras are the secondary changes produced in a disease. Upadrava is said to be originated at later stage of a disease, it occurs from the main disease [3].

This morbid process occurring during a disease may be minor or major ailment. It is a morbid event, which develops by the factors responsible for the manifestation of the main disease. It is an episode which develops after the manifestation of main disease and subsides by giving treatment to main disease. Treatment is not antagonistic to main disease [4]. Our body loses its power when a disease process is going on for long period and upadrava originates after that. i.e. it occurs in the later period when the dosha aggravates more and vyadhi kshamatva is decreased due to ojakshaya. In prameha Acharyas had mentioned upadrava according to involvement of dosha. All varieties of prameha if not treated at proper time, turned into madhumeha and then become incurable [5]. A person who is born with prameha (kulaja) or who has become a madhumehi is not curable [6]. In current study a drug was selected from Sushrut Samhita which is described as having Rasayana properties to combat the dhatukshaya in vaticpramehi. Acharya Sushruta described the treatment of asadhya Madhumeha with Shilajeet as it can destroy all types of diseases [7]. Shilajeet is a thick, sticky tar like substance with a colour ranging from white to dark brown (later is more common) [8]. The word

The word Sila denotes rock, which is considered as one of the most important source. Term Jatu denotes a blackish brown substance, which is similar to 'laksha'. Thus 'Silajatu' is the exudates of rocks having blackish brown colour and oozes out from steep rocks of mountain during summers because of intense sun heat. Shilajeet is a substance mainly found in the Altai, Himalaya, and Caucasus mountains of Central Asia. The colour range varies from a yellowish brown to pitch-black, depending on Composition. For use in Ayurvedic medicine the black variant is considered the most potent. Shilajeet has been described as 'mineral oil', 'stone oil' or 'rock sweat', as it seeps from cracks in mountains due mostly to the warmth of the Sun heat [9]. The composition of Silajatu has been investigated numerous times in both India and the former USSR, and it depends on the location where it is found. It has been reported to contain at least 85 minerals in ionic form, as well as triterpenes, humic acid and fulvic acid [10]. Shilajatu having the smell of cow's urine is considered best for the therapeutic purposes. Lauha Silajatu is considered best for Rasayana therapy [11].

AIM AND OBJECTIVES

1. Aetio-pathological study about vatic Prameha upadrava.
2. To assess the efficacy of Shilajeet in the management of vatic prameha upadrava

MATERIAL AND METHOD

The study was conducted under a strict protocol to prevent bias to reduce the sources of error in the study. This study was conducted under the following steps

1. Selection of patients
2. General observation

1. Administration of drug
2. Follow up study
3. Assessment of progress

Selection of Patients

The patients for the clinical study were selected from OPD and IPD of NIA Hospital and SSBH, Jaipur after screening them as per Ayurvedic and Modern criteria for complication of prameha. Selection was carried out on the basis of relevant history, signs and symptoms and laboratory investigations. A written information and consent form had been given to the patients. The patients were explained about the purpose, procedures and possible side-effects of the trial.

Criteria for the selection of the patient

Inclusion criteria:

1. Patient in the age group above 18 yrs irrespective of either sex.
2. Diagnosed case of type 2 diabetes mellitus.
3. Patient having complication which are mentioned in modern and Ayurvedic classics.

Exclusion criteria:

1. Patient in the age less than 18 yrs.
2. Patients with major complication like hypertension, cardiopathy, nephropathy (end stage) etc.
3. Patient with secondary DM caused due to pancreatectomy, cystic fibrosis of pancreas.
4. Pregnant woman and those who did not want to participate.

Diagnostic Criteria:

The following criteria were developed to select the cases on clinical ground, which is based on the signs and symptoms, described in Ayurvedic and Modern texts and laboratory investigations. All the patients were assessed on the basis of assessment criteria as follows.

Subjective Parameters :

Prabhoota Mootra, Avila Mootrata, Kshudha-Adhikya, Trishna, Udavarta, Hridgraha, Stambha, Kara- pada Daha, Kara- pada, Suptata. Anidra, Daurbalya, Arochak, Avipaka, Vivandha, Sotha, Sandhi-shula, Kampa Rukshata, Swasa, Kasa, Murccha, Bhrama. Bibheti, Abhiksnam Dhyati, Vyathitendriya Duschaya, Durmana, Ksama, Putimamsa- Pidika.

Objective Parameters :

The following laboratory criteria were used to investigate the patients- Haematological- Hb%, TLC, DLC, ESR, HbA1c, Biochemistry- FBS, PPBS, Lipid profile; Urine examination- Routine and Microscopic; Specific test -TFTs and nerve conduction test. All these laboratory tests were conducted in Central laboratory, NIA, Jaipur

Administration of drug :

Shilajeet, described in Susrut Samhita was selected for the research work. 35 clinically diagnosed case were administered the drug. But out of them 32 patients had completed the trial. The drugs were prepared in the pharmacy of NIA (National Institute of Ayurveda, Jaipur) according to classical method. Drug -Suddha Shilajeet capsule; Dose - 500 mg / capsule (1 capsule twice daily before meal); Anupan - Milk (20 ml); Duration of the trial - 2 months.

Type of trial: Simple Randomized

Diet and Regimen :

Patient were asked to indulge in morning & evening walk for atleast 30 minutes along with other physical exercises. They were advised to avoid sweets, salts, pulses, curd, spicy, oily and other kapha & vata vitiating ahar- vihar.

Follow up Study

Patients were followed every 15 days.

Laboratory investigation was repeated after complete treatment.

Improvement and other side effects were noted.

Assessment of progress

After the completion of the treatment, the results are assessed by adopting the following criteria.

1. Improvement in signs and symptoms of disease on the basis of symptoms score.
2. Improvement in laboratory investigation on the basis of laboratory reports.

A proforma is designed to assess patient's Dasavidha- pariksha, Pancanidana, before and after administration of drug

Subjective assessment

It is based on the feelings of patients, so researcher has to depend on his patient for assessment. It is known as 'simple verbal scale'. In this particular research work, subjective criteria were taken from the reference book- 'Developing Guidelines for Clinical Research Methodology in Ayurveda', IPGTR & A, Jamnagar, 2011, by Prof. M.S. Baghel and according to Ayurvedic texts.

Objective assessment :

The patients were assessed for the relief of symptoms based on investigation reports of the patient, before and after administration of drug.

Observation and result :

The study was carried out in Diabetic patients to assess various profiles viz. demographic, constitutional, clinical and laboratory profiles. The results of therapy were assessed on the basis of different subjective and objective parameters. Various Observations made during the current clinical trial are summarized as follows:

In the present study total 35 patients were registered. Out of which 32 patients completed the study and 2 patients did not complete the trial without any genuine cause, 1 patient left against medical advice.

All the patients registered for the trial were divided into three sub-group for the analysis of data. Patients were divided on the basis of HbA1c level.

1. Gr-A - 6.5 - 7% (n=8)
2. Gr-B - 7.1 - 8.5% (n=14)
3. Gr-C - >8.5 (n=10) {Canadian Diabetes Association Clinical Practice Guidelines Expert Committee}

Wilcoxon matched - Pairs signed rank test for the paired test used for the analysis the following data.

Subjective improvement

After the completion of the trial it was observed that there was considerable improvement in the feeling of wellbeing and physical and mental weakness in all the three Group (A, B, C). The improvement found in symptoms are as follows -

Group A

88.2 % improvement in Prabhuta-mutrata, 100 % in Avila- mutrata, 76.9 % in Kara pada daha, 80 % in Kara pada suptata, 33.3 % in Udavarta, 83.3 % in Hridgraha, 44.4 % in Anidra, 58.8 % in Daurbalya, 60 % in Kshudha-adhikya, 75 % in Trishna, 60 % in Avipaka, 14.28 % in Vivandha, 33.33 % in Sotha, 63.63 % in Sandhi-shula, 53.84 % in Rukshata, 71.42 % in Swasa, 100 % in Kasa, 100 % in Murccha, 83.33 % in Bhrama, 81.81 % in Bibheti (timidity), 36.36 % in Abhiksnamdhyati, 33.33 % in Duschaya, 57.87 % in Durmanah, 25 % in Kshama and 100 % in Putimamsa-pidika

The above result reveals that there is improvement in Prabhuta- mutrata, Avila-mutrata, Kara pada daha, Kara pada suptata, Hridgraha, Sandhi-shula, Rukshata and Kasa. The action of Shilajeet as a Rasayana can be assumed here. According to Caraka the means by which we can get perfect Rasa and Dhatu is called Rasayan and that type of effects definitely gives more stability to the affected dhatus and subsequent clinical work also shows the result.

Group B

100 % improvement was found in Prabhuta-mutrata, 100 % in Avila-mutrata, 73.7 % in Kara pada daha, 53.8 % in Kara pada suptata, 60 % in Udavarta, 71.4 % in Hridgraha, 40 % in Anidra, 58.8 % in Daurbalya, 60 % in Kshudha-adhikya, 71.42 % in Trishna, 75 % in Avipaka, 57.14 % in Vivandha, 66.66 % in Sotha, 58.33 % in Sandhi-shula, 50 % in

Rukshata, 57.14 % in Swaca, 100 % in Kasa, 100 % in Murccha, 50 % in Bhrama, 54.54 % in Bibheti(timidity), 53.84 % in Abhiksnamdhya, 33.33 % in Duschaya, 33.33 % in Durmanah, 30 % in Kshama and 33.33 % in Putimamsa-pidika.

The above results shows that there is marked improvement in the symptomatic parameters in Group B than Group A. P value is extremely significant in Prabhuta-mūtratā, Kara pādādhā, Kara pādasuptatā, Daurbalya, Sandhi-shula, Bibheti(timidity), Abhiksnamdhya and Durmanāh. It seems that it is also due to the Rasāyana properties of Shilajeet, In Group B the HbA1c level is 7.1-8.5. which we can say the acute condition of the disease. As in VatikPramehaUpadrava there is excessive and immediate loss of dhatus, so application of Rasayan drugs at this stage showed effective result. Acarya Caraka also said from Rasayana we may achieve the proper and more stable dhatus.

Group C

100 % improvement was found in Prabhuta-mūtratā, 100 % in Avila-mūtratā, 52.9 % in Kara pādādhā, 66.7 % in Kara pādasuptatā, 33.3 % in Udāvarta, 66.7 % in Hridgraha, 40 % in Anidrā, 58.33 % in Daurbalya, 66.7 % in Kshudhā- adhikya, 83.33 % in Trishnā, 100 % in Avipāka, 57.14 % in Vivandha, 44.44 % in Sotha, 50 % in Sandhi-shula, 33.33 % in Rukshatā, 54.54 % in Swāca, 100 % in Kāsa, 100 % in Murcchā, 66.66 % in Bhrama, 60 % in Bibheti (timidity), 61.53 % in Abhiksnamdhya, 18.75 % in Duschāya, 42.85 % in Durmanā hand 22.22 % in Kshama.

The above result reveals that the drug Shilajeet is able to enter the micro channel and perfectly breakdown the pathological process of prameha. Prabhuta-mūtratā and Avila-mūtratā have been reduced completely. There is improvement in other symptoms also. The HbA1c level in Group C is > 8.5. It can be categorized under uncontrolled Diabetes.

Objective improvement

Group A

20.3 % increase in FBS, increase of PPBS is 15.5 %, 15 % increase in serum triglyceride level, 24.2 % increase in serum cholesterol, 7.2 % increase in HDL, 27.8 % in LDL, TLC decreased upto 9 %, 1.5 % relief in HbA1c level, 2.4 % improvement in Hb %, 1.8 % relief in ESR.

Group B

5.06 % decrease (relief) in FBS, 8.02 % relief in PPBS, 16.14 % improvement in HbA1c level, 3.68 % decrease in Serum triglyceride level, 5.12 % decrease in serum cholesterol, 5.25 % decrease in HDL, 8.17 % improvement in LDL, TLC decreased upto 16.38 %, 1.5 % relief in, 4.85 % improvement in Hb %, 18.95 % relief in ESR.

Group C

17.66 % relief in FBS, improvement in PPBS is 17.19 %, 17.71 % decrease in Serum triglyceride level, 52.64 % decrease in Serum cholesterol, 0.99 % decrease in HDL, 16.14 % relief in LDL, TLC decreased upto 6.44 %, 18.76 % improvement in HbA1c level, 4.73 % decrease in Hb %, 22.73 % relief in ESR.

The result of the drug on objective parameters in Group A, Group B and Group C showed that there is no significant effect in laboratory parameters like FBS, PPBS, Serum triglyceride, Serum cholesterol, LDL, HDL, TLC, BMI, Waist-Hip ratio and HbA1c level in Group A. But in Group B and in Group C there is mild improvement in FBS,

PPBS, Serum triglyceride, Serum cholesterol, LDL and HbA1c level. The drug showed mild improvement in Hb % in Group A and Group B and decrease in group C. The drug Shilajeet showed mild improvement in ESR.

So, the overall effect of the trial drug on Subjective and Objective parameters shows that there is marked improvement in subjective parameters (Sthoolaupadrava) than the lab parameters (Anu Upadrava). In case of Subjective parameters the Rasayan effect of Shilajeet has been proved. But in objective parameter Shilajeet showed mild improvement. Thus it is proved that the drug Shilajeet is more effective in gross physical impaired conditions (Symptoms) than the minute laboratory parameters. The rasa of Shilajeet is katu-tikta- kashaya and in disease "Kapha", the main doṣa for Prameha get subside naturally and on the other hand rasas of Shilajeet is also responsible for aggravation of Vatadoṣa, that may be one of the leading cause for the mixed effect of the therapy.

CONCLUSION

1. The result obtained out of the present study indicated that there is more improvement in subjective parameters than the objective parameters.
2. Daurbalya is the most common complication of Prameha.
3. Effect of trial drug Shilajeet capsule on Subjective parameters shows marked improvement.
4. In Laboratory parameters the result was not satisfactory.
5. Healthy dietary, behavioral regimen and regular medical checkup along with proper medication is the only solution to keep away from complication.

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