

SHILAJIT: EVALUATION OF ITS EFFECTS ON BLOOD CHEMISTRY OF NORMAL HUMAN SUBJECTS

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Received : 03-02-2003

Accepted: 26-08-2003

ABSTRACT: The effect of Shilajit on blood chemistry was studied in normal human volunteers. Administration of two gms of Shilajit for 45 days did not produced any significant change in physical parameters i.e. blood pressure, pulse rate and body weight and similarly no change was observed in hematological parameters. A signification reduction in Serum Triglycerides, Serum cholesterol with simultaneous improvement in HDL Cholesterol was seen, besides Shilajit also improved antioxidant status of volunteers. Results of study suggest hypolipidemic and strong antioxidant activity of Shilajit.

INTRODUCTION:

Shilajit is a bituminous substance which is compact mass of vegetables matter composed of dark, red, gummy matrix interspersed with vegetable fibres, sand and earthy matter (1). In 'folklore' medicine Shilajit has been implicated in several clinical conditions and is being prescribed by Ayurvedic physicians for the treatment of diabetes, jaundice, gall bladder disease and renal calculi, enlarged spleen, digestive troubles, fermentative dyspepsia, adiposity, anasarca, anuri, hysteria, neurological diseases, amenorrhoea, dysmenorrhoea and menorrhagia, genitor – urinary diseases, tuberculosis, leprosy, eczema, anemia, anorexia, chronic bronchitis, asthma, fracture of bones and many other clinical conditions. It has also been claimed that "There is hardly any curable diseases which cannot be controlled / cured with the aid of Shilajit" (2,3,4) Survey of literatures reveals that there are only a few studies which have been carried out systematically to understand therapeutic and biological action of Shilajit. Aqueous suspension of Shilajit

has been found to have analgesic and anti – inflammatory activity without any toxic effect given in dose of 1 gm./kg body weight to albino mice (5). More recently researchers have indicated antistress and adaptogenic (6) and antioxidant action of Shilajit (7). Ghoshal and Bhattacharya (1996) reported that processed Shilajit provides significant antioxidants defence as compared to native Shilajit, which has weak antioxidant action (8). Various Therapeutic actions of Shilajit have been attributed to its active principles fulvic acid and dialphabenzopyrones. Although Shilajit has been claimed to cure several diseases, its effect on blood chemistry, organ functions and antioxidant action has not been examined *in vivo*, hence the present study is an attempt to examine the effect of Shilajit on blood chemistry of normal human subjects.

MATERIALS AND METHODS

30 medical students from National Institution of Ayurveda, Jaipur participated in the present

study ranging in age from 16 to 30 years. A written consent was obtained from each of them and they were appraised of the purpose of study. Care was taken to ensure that all the subjects were from similar socioeconomic status, symptom free, without any obvious clinical disorder on examination, not taking any drug therapy, vitamins and health booster, non smokers and lacto vegetarian and non pregnant. Subjects were administered with 2 gms Shilajit per day in the form of capsules of 500 mg. each.

Crude Shilajit was procured from Pharmacy of National Institute of Ayurveda, Jaipur, and purified by one of us (V.S) who is an Ayurvedic Physician himself by “*Agnitapi*” method. (9, 10) Purification of Shilajit by *Agnitapi* method essentially involves four steps. 1. Soaking in water/preparation of solution of Shilajit. 2. Filtration – to remove impurities and practicles. 3. Boiling of clear watery filtrate until a thick viscous liquid is obtained. 4. Drying of thick viscous liquid obtained in preceding step in incubator at 50⁰C. The purity of processed Shilajit so obtained was assessed by Ayurvedic method- “*Jalapariksha*” and “*Agnipariksha*”. Shilajit has a characteristic solubility, shape, from and smoke. Capsules of 500 mg. of processed and purified Shilajit were prepared. Processed Shilajit was analyzed at Dabur Research Foundation for its active principles. Figure 1 shows fingerprints of purified Shilajit relation to standard. Its chemical analysis is given in Table 1. All the subjects were clinically examined by one of us (V.S) and their body weight, pulse rate, blood pressure and history of any past illness were carefully recorded. Double blind placebo study was carried out and 20 subjects were administered with two grams Shilajit per day (4 capsules of 500 mg. each) under the supervision of Ayurvedic physician and 10 subjects were given sugar capsules (placebo).

Subjects were unaware of the contents of capsule.

Blood samples were drawn before and after 45 days of supplementation of Shilajit and analyzed of Sugar, Urea, Creatinine, Total Protein, Albumin, A/G Ration, Uric Acid, SGOT, SGPT, Alkaline Phosphatase, Triglycerides (TG), Cholesterol, HDL, LDL and VLDL on Merck selectra auto analyzer using standard kits. SOD was analysed by kits supplied by Randox, Vitamin C and E analysed by manual methods (11,12)

RESULTS AND DISCUSSION

Study was conducted on 30 normal healthy human subjects in the age range 16-30 years. Median age 24 years, out of which 20 subjects were given 2 gms of purified Shilajit and 10 were placebo controls. Processed Shilajit was procured from crude (native) Shilajit through several steps of purification. Native Shilajit is found to be contaminated with polymeric quines, microbial debris and heavy metals (13, 14). These contaminants are required to be removed by purification. Purified Shilajit improves its beneficial effects in living system. (Ghosal and Bhattacharya 1996).

Processed Shilajit was found to be positive for benzopyrones and fulvic acid contents, which are considered as its active principles. Purified Shilajit, used in present study contains 6.61% (w/w) fulvic acid (Table 1). Supplementation of 2 gms Shilajit for 45 days to normal healthy subjects did not produce any significant change in blood pressure, pulse rate and body weight. Similarly no change in hemoglobin level and cell counts could be appreciated. Effect of processed Shilajit on biochemical parameters is summarized in Table 2, which shows that it has no significant ($p > 0.05$) effect on blood sugar, urea, creatinine, uric acid, total protein,

albumin, SGOT, SGPT and Alkaline Phosphatase level. It has to be borne in mind that the study was conducted in normal conditions in normal subjects and most of the drugs do not affect biochemical parameters in normal conditions. But an important observation emerges from this study that Shilajit does not adversely affect liver and kidney functions, which is evident from SGOT, SGPT, Alkaline phosphatase, Urea, Creatine and Uric acid levels. However at the same time there was a significant reduction in serum TG, Cholesterol, LDL Cholesterol and VLDL Cholesterol levels and significant improvement in HDL Cholesterol level. Decrease in serum TG and Cholesterol level ($p < 0.01$) with simultaneous increase in HDL suggests its hypolipidemic and cardio protective activity. Further more its effects on serum SOD; Vitamin E and Vitamin C have also been examined. SOD is one of the important antioxidant enzymes, which removes the super oxide radical in the front line of defense against oxidative stress, while vitamin C and E are important nutrient antioxidants, which prevent lipid per oxidation. Shilajit significantly increased SOD, Vitamin E and Vitamin C levels of

blood ($p < 0.01$). Increase in antioxidant level suggests its sparing effect on antioxidants and strengthens the protective system to prevent damages caused by reactive oxygen species and also against the oxidative stress. Antioxidant activity of Shilajit could be attributed to its fulvic acid contents. Fulvic acid plays as a bi-directional super antioxidant i.e. as electron donors and acceptors, depending upon the need for balance in the situation. If it encounters free radicals with unpaired positive electron it supplies an equal and opposite negative charge to neutralize it, likewise, if free radicals carry a negative charge, the fulvic acid molecule can supply positive unpaired electron to nullify that charge. Ghosal and Bhattacharya (1996) has also, observed in an *in vitro* study that processed Shilajit provides a significant oxidative defense by scavenging singlet oxygen (8). Result of the study suggests that Shilajit has hypolipidemic and antioxidant action. However that extracts mechanism of action is not yet fully understood and further study is needed to examine its effects in particular diseases, which alter these biochemical parameters.

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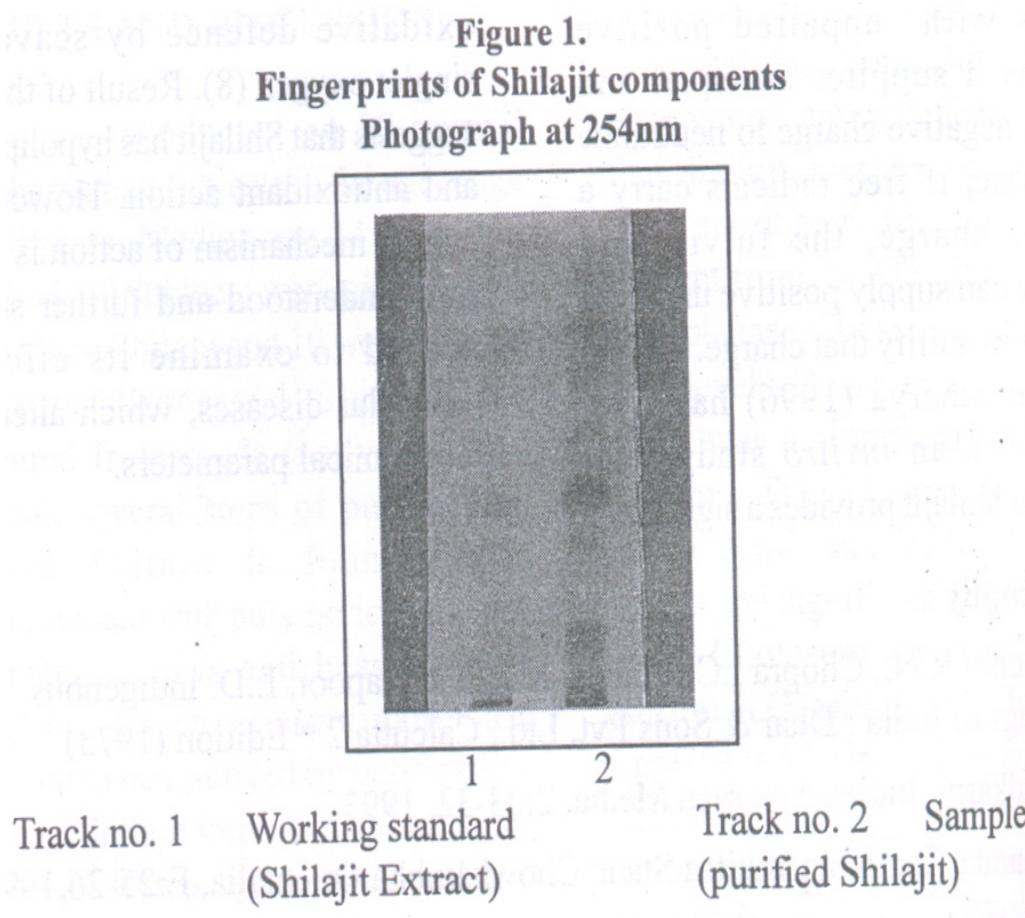


TABLE 1
Analysis of Drug (Shilajit)
Dabur Research Foundation Analytical Report – No _ 050622

TEST Description	SAMPLE (PURIFIED) Dark brown powder
Identification	
Test for Benzopyrones	Positive
Test for Fulvic acids	Positive
PH. 10% w/v Aq. Dispersion	6.37
Moisture content (KF) (% w/w)	9.50
Water soluble extractive value (% w/w)	92.13
Total ash content (% w/w)	15.35
Acid insoluble ash content (% w/w)	1.25
Assay as crude Fulvic Acid (% w/w)	6.61

Table 2
Effect of Shilajit on blood chemistry (Values are Mean \pm SD)

S. NO	PARAMETER	Group 1 (Placebo) n = 10 (without supplementation)		Group 2 n = 20 (Supplementation of Shilajit)	
		Before	After	Before	After
01	SUGAR (mg/dl)	76.3 \pm 8.28	76.1 \pm 7.85	79.3 \pm 8.00	75.8 \pm 7.18
02	UREA (mg/dl)	24.0 \pm 3.68	22.8 \pm 5.05	26.5 \pm 6.00	24.1 \pm 5.70
03	CREATININE (mg/dl)	1.0 \pm 0.118	0.97 \pm 0.11	0.99 \pm 0.13	0.96 \pm 0.22
04	URIC ACID (mg/dl)	4.67 \pm 1.06	4.55 \pm 1.11	4.6 \pm 0.65	4.3 \pm 0.65
05	TOTAL PROTEIN (g/dl)	7.09 \pm 0.27	6.99 \pm 0.30	7.05 \pm 0.35	7.1 \pm 0.237
06	ALBUMIN (g/dl)	3.97 \pm 0.24	3.90 \pm 0.18	3.95 \pm 0.201	4.00 \pm 0.087

07	A/G RATIO	1.26 ± 0.06	1.22 ± 0.10	1.21 ± 0.083	1.25 ± 0.102
08	SGOT (U/L)	29.4 ± 6.03	28.4 ± 5.64	32.2 ± 6.12	28.7 ± 7.81
09	SGPT (U/L)	19.7 ± 2.10	20.4 ± 2.57	20.8 ± 3.02	19.3 ± 2.49
10	ALK. PHOSPHATASE (U/L)	154.9 ± 32.7	153.4 ± 34.7	160.1 ± 22.9	151.6 ± 26.32
11	TRIGLYCERIDES (mg/dl)	114.1 ± 40.19	115.6 ± 40.76	116.9 ± 24.6	92.7 ± 39.12*
12	CHOLESTEROL (mg/dl)	142.9 ± 13.92	142.3 ± 12.78	145.3 ± 15.33	125.1 ± 17.17*
13	HDL (mg/dl)	41.57 ± 1.38	41.4 ± 2.24	41.2 ± 2.30	43.6 ± 1.99*
14	LDL (mg/dl)	78.55 ± 7.37	77.77 ± 6.25	81.8 ± 8.11	63.30 ± 7.36 *
15	VLDL (mg/dl)	22.83 ± 7.99	23.13 ± 8.15	23.30 ± 4.92	18.50 ± 7.82*
16	SOD (U/L)	186.5 ± 37.07	188.9 ± 35.79	160.5 ± 13.2	200.7 ± 2.81*
17	VIT C (mg/dl)	0.71 ± 0.08	0.75 ± 0.09	0.72 ± 0.09	0.99 ± 0.09*
18	VIT E (mg/dl)	0.98 ± 0.09	1.03 ± 0.11	0.95 ± 0.11	1.28 ± 0.13 *

Statistical comparison was done before and after values: *p<0.01; rest not significant p>0.05.