



ASSESSMENT OF EFFECT OF TWO METHOD SHODHITA SHILAJIT ON BLOOD GLUCOSE LEVELS ON NEWLY DIAGNOSED HYPERGLYCEMIC SUBJECTS

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ABSTRACT

Shilajit is one of the most widely used drug in the treatment of many ailments in day to day practice. In general all metals, minerals and animal product, if not purified and processed properly, show some untoward or adverse effects on humans. Because of commercialization and rapid growth of pharmaceutical industry, lot of adulteration is seen in the raw materials of Ayurveda. Hence, after proper identification of them, Shodhana is to be carried out based on classical references. In Rasashastra different methods of Shodhana are mentioned for Shilajit. In the present study following two methods of Shodhana were done (Ref R.R.S) and comparative effect was observed on blood glucose level of hyperglycemic subjects.

1-Method A- Yavakshara Kanji – Gomutra---Bhavana method

2-Method B- Yavakshara –Kanji- Guggulu--- Swedana method

Keywords: Shilajatu, Shilajit, Shodhana, yavakshara, hyperglycemia, Guggulu, Gomutra

INTRODUCTION

Shilajit is a herbo-mineral drug, which oozes out from a special type of mountain rocks in the peak summer months. It is found at high altitudes ranging from 1000 to 5000 meters. The active constituent of Shilajit consists of dibenzo-alpha-pyrone and related metabolites, small peptides (constituting non-protein amino acids), some lipids and carrier molecules (fulvic acids)^{1, 2}. Standard Shilajit contains at least 5-7% dibenzo-alpha-pyrone¹⁻³. Shilajit finds extensive use in Ayurveda, for diverse clinical conditions. For centuries people living in the isolated villages in Himalaya and adjoining regions have used Shilajit alone or in combination with other plant remedies to prevent and combat problems with diabetes⁴. Medical researchers have taken a more serious interest in determining if the claims regarding the antidiabetic effects of Shilajit have scientific merit. Studies done by Gupta⁵ and Bhattacharya⁶ have also reported the antidiabetic actions of shilajit. In the light of the above data, the objectives of the present study was Assessment of effect of two method shodhita Shilajit on blood glucose levels on newly diagnosed hyperglycemic subjects.

Aims and Objective

To do Assessment of Effects of two methods shodhita Shilajit (Ref-R.R.S) on newly diagnosed hyperglycemic subjects.

MATERIALS AND METHODS

Selection of raw material

Market sample of Gomutra Gandhi Shilajit was collected and authenticated from Post Graduate Department of Rasashastra K.L.E Society's Shri B.M.K Ayurveda Mahavidyalaya, Belgaum, Karnataka, India

Shilajatu shodhana was done based on following two methods

1-Method A- yavakshara –kanji – gomutra---bhavana method⁹

2-Method B- yavakshara –kanji- guggulu--- swedana method

Clinical Study

Ethical clearance was taken for clinical trial

The comparative effect was assessed in 60 newly diagnosed hyperglycemic subjects who were not taking any medicines. The subjects were divided into 2 groups (A&B) comprising of 30 subjects in each group randomly.

Group A-

Method 1 formula – 500mg/day in a single dose on empty stomach for 21 days

Group B-

Method 2 formula – 500mg/day in a single dose on empty stomach for 21 day

Inclusive criteria

Newly diagnosed hyperglycemic Subjects(3-6 months old), irrespective of sex, age, occupation, religion etc who were not taking any medication for Diabetes, were randomly selected from OPD, IPD, Diabetic camps of K.L.E.Society's Ayurveda Hospital, Shahapur, and Belgaum.

Exclusive criteria

More than 3-6 month old hyperglycemic subjects, who were taking medication for hyperglycemia & Subjects who were not willing were excluded.

Discontinuation criteria

Subjects whose blood glucose levels & chief signs and symptoms did not come down or raised & who developed any side effects/ illness during the trial regime were advised to discontinue the drug.

RESULTS

Table 1: Group A -FBS* before and after drug trial

Blood glucose	FBS Before Drug trial	FBS After Drug trial
61-80	-	03
81-100	-	13
101-120	11	08
121-140	11	04
141-160	06	01
161-180	01	01
181-200	01	-
201-220	-	-

FBS before drug trial >120 19 subjects & ≤ 120, 11 subjects were there After drug trial >120, 6 subjects & ≤ 120, were 24 statistically significant. ($\chi^2 = 12.109$, DF=1, P<0.005)

Table 2: Group B- FBS* before and after drug trial

Blood glucose	FBS Before Drug trial	FBS After Drug trial
61-80	-	05
81-100	04	03
101-120	07	04
121-140	11	15
141-160	06	02
161-180	02	01
181-200	-	-
201-220	-	-

FBS before drug trial >120 were 19 subjects & ≤ 120, were 11 subjects were there. After drug trial >120, 18 subjects & ≤ 120, were 12 statistically not significant. ($\chi^2 = 0.25$, DF=1, P>0.5)

Table 3: Group A - PPBS before and after drug trial**

Blood glucose	PPBS Before Drug trial	PPBS After Drug trial
61-80	-	-
81-100	-	01
101-120	-	06
121-140	05	06
141-160	05	06
161-180	08	02
181-200	03	01
201-220	-	01
221-240	-	07
241-260	07	-
261-280 above	02	-

PPBS before drug trial >140 were 25 subjects & ≤ 140, 5 subjects were there. After drug trial >140, 17 subjects & ≤ 140, were 13 statistically significant. ($\chi^2 = 6.035$, DF=1, P<0.025)

Table 4: Group B - PPBS before and after drug trial**

Blood glucose	PPBS Before Drug trial	PPBS After Drug trial
61-80	-	-
81-100	-	-
101-120	-	-
121-140	01	04
141-160	05	09
161-180	06	03
181-200	04	05
201-220	05	01
221-240	-	-
241-260	02	06
261-280 above	07	02

FBS before drug trial >140 were 29 subjects & ≤ 140, 1 subject was there. After drug trial >140, 26 subjects & ≤ 140, were 4 statistically not significant. ($\chi^2 = 2.083$, DF=1, P>0.1)

Table 5: Group A & Group B - FBS* levels Comparison of after drug trial

Blood glucose after drug trial	FBS Group A	FBS Group B
61-80	03	05
81-100	13	03
101-120	08	04
121-140	04	15
141-160	01	02
161-180	01	01
181-200	-	-
201-220	-	-

In case of Group A after drug trial FBS>120 were 6(20%) and ≤ 120 were 24(80%) whereas in Group B FBS >120 were 18(60%) and ≤ 120 were 12(40%) statistically difference is significant this shows Group A is having more better results than Group B. ($\chi^2 = 10$, DF=1, P<0.005)

Table 6: Group A & Group B - PPBS levels Comparison of after drug trial**

Blood glucose	PPBS Group A	PPBS Group B
61-80	-	-
81-100	01	-
101-120	06	-
121-140	06	04
141-160	06	09
161-180	02	03
181-200	01	05
201-220	01	01
221-240	07	-
241-260	-	06
261-280 above	-	02

In case of Group A after drug trial PPBS>140 were 18(60%) and ≤ 140 were 12(40%) whereas in Group B FBS >140 were 26(86.7%) and ≤ 140 were 4(13.3%) statistically difference is significant this shows Group A is having more better results than Group B. ($\chi^2 = 5.454$, DF=1, P<0.025)

Table 7: Group A - Comparison of FBS* Mean reduction values before & after drug trial

Before	After	Change (reduction)	Paired t	DF	P	Significance/not significant
129.8±22.23	104.9±22.63	24.9±10.25	13.301	27	<0.001	Significant

Table 8: Group A -Comparison of PPBS Mean reduction values before & after drug trial**

Before	After	Change (reduction)	Paired t	DF	P	Significance/not significant
190.37±51.21	162.3±45.76	28.07±20.87	7.366	29	<0.001	Significant

Table 9: Group B - Comparison of FBS* Mean reduction values before & after drug trial

Before	After	Change (reduction)	Paired t	DF	P	Significance/not significant
130.23±21.76	116.73±24.86	13.5±5.50	13.442	29	<0.001	Significant

Table 10: Group B - Comparison of PPBS Mean reduction values before & after drug trial**

Before	After	Change (reduction)	Paired t	DF	P	Significance/not significant
202.96±45.92	187.03±48.49	15.93±8.69	10.031	29	<0.001	Significant

Table 11: Group A & Group B- Comparison of FBS* Mean reduction values before & after drug trial

	T	DF	P	Significance/not significant
FBS	5.367	58	<0.001	Significant
PPBS	2.941	58	<0.01	Significant

Mean reduction in FBS is more in Group A compared to Group B. Mean reduction in PPBS is more in Group A compared to Group B.

DISCUSSION

Although the precise mechanism of action of Shilajit cannot be explained but initially hyperglycemia or diabetes is suggested to result from islet inflammation, followed by infiltration of activated macrophages and lymphocytes in the inflammatory focus. These cells might be the source of the cytotoxic oxygen radicals¹⁰. Shilajit has been reported to reduce macrophage and lymphocyte activation and migration, as a part of its immunomodulatory activity⁶. Moreover, being an antioxidant it will prevent damage to the pancreatic islet cell induced by the cytotoxic oxygen radicals⁶⁻⁸.

In the present study, treatment with Shilajit 500 mg/ day for 21 days produced significant hypoglycemia. Gupta *et al*⁵ suggested that long-term treatment with Shilajit increases the number of β -cells of pancreas, i.e. pancreatotrophic action, which may result in better sensitivity of pancreatic β -Cells with prompt secretion of a large quantity of insulin in response to hyperglycemia.

CONCLUSION

Yavakshara-kanji-Gomutra shodhita Shilajit & Yavakshara-kanji-Guggulu Shodhita Shilajatu, both have significant reduction of blood glucose level in subjects suffering from short history of hyperglycemia

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