



ISSN: 2456-0057

IJPNE 2019; 4(1): 985-987

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www.journalofsports.com

Received: 07-11-2018

Accepted: 08-12-2018

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Clinical efficacy of polyherbal unani formulation in patients of newly diagnosed diabetes mellitus - A case series study

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Abstract

Diabetes mellitus (DM) is a metabolic disorder with multiple etiologies, characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. It may lead to many acute and chronic complications. Such type of chronic complications is mainly due to the result of longstanding damage to blood vessels. These complications are mainly classified as microvascular due to basement membrane thickening or macrovascular due to accelerated atherosclerosis. The major microvascular complications are diabetic retinopathy, diabetic neuropathy and diabetic nephropathy. Complications of diabetes are totally due to poor glycemic control. Unani Medicine is the thrusting area of research to control or reduce the complications of diabetes. Several Unani drugs (*mufrad* and *murakkab*) exhibit anti-diabetic activity, nootropic activity, antioxidant activity, immunomodulator activity such as *Gilo*, *Saadkofi*, *Jatamani*, *Berge Sena*, *Darhald*, *Post Kachnal*, *Aqerqarha*, *Azaraqui*, *Beesh*, *Balehhar*, *Tukhme Khurfa*, *Dammul Akhwain*, *Kabab Chini*, *Darchini*, *Tukhm Methi*, *Gurmar Booti*, *Asgand* etc., and some compounds are *Safoof-e-Ziabetus*, *Qurs-e-Ziabetus*, *Qurs-e-Gulnar*, *Qurs-e-Tabsheer*, *Habb-e-Asab*, *Habb-e-Azaraqui*, *Kushia Qalai* etc. Aim of this case series study is to explore the benefits of Polyherbal Unani Formulation on their scientific parameters to reduce the burden of diabetes.

Keywords: Ziabetus; diabetes mellitus; polyherbal unani medicine

Introduction

Diabetes mellitus (DM) is a metabolic disorder with multiple etiologies, characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both [1]. In Unani classical text diabetes is mentioned by eminent Unani scholars like *Razi*, *Majoosi*, *Sina*, *Jurjani*, *Zuhar*, *Baghdadi*, with various names such as; *Ziabetus*, *Zalaqul Kkuliya*, *Dawwarah*, *Moattasha*, *Dolab*, *Atsha*, *Intesae Anmas*, *Barkar*, *Barkarya*, *Qaramees* etc. [2-8] Long term effect of diabetes leads to various complications viz., diabetic nephropathy, neuropathy, retinopathy, diabetic foot, charcot joints and sexual dysfunction [8-9]. People with diabetes are at increased risk of cardiovascular, peripheral vascular and cerebrovascular diseases [10]. Worldwide prevalence of diabetes was estimated to 8.3% with age between 40 to 59 years and 46% of cases undiagnosed in 2013, with India alone accounting for 65.1 million and in China 98.4 million patients. It may shoot up to 55% by the year 2035. Half of the people with diabetes do not know they have it, 80% people with diabetes live in low and middle income countries, half of the people who die from diabetes are under the age of 60. Every six seconds a person dies from diabetes. The cost of diabetes care is enormous and escalating worldwide. It is estimated 11% (548 billion USD) is spent on diabetes treatment [11]. According to Unani philosophy, diabetes is considered as disease of Kuliya and it is due to four causative factors (i) Zoaf-e-Kuliya (weakness of kidney) (ii) Ittesa-e-Kuliya wa majrae Baul (dilatation of kidney and tubule) (iii) Su-e-Mizaj Haar Kuliya (derangement of temperament of kidney due to heat) and (iv) Su-e-Mizaj Barid Kuliya (derangement of temperament of kidney due to cold) [2-8].

Presently, sulphonylureas, biguanides, insulin and including DPP-4 Inhibitors are used to manage the diabetes [12]. Long term usage of these drugs leads to several complications and adverse effects visually; hypoglycemia, renal problem,

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gastro intestinal tract disturbance and sometimes cardiac problems [8].

Material Methods

This small preliminary study evaluates the safety and efficacy of Polyherbal Unani Formulation for the management of *Ziabetes* (Diabetes) with polyuria, polydipsia, polyphagia and tiredness with abnormal blood sugar level FBS, PPBS). Before establish the study informed consent was taken from the subjects. Unani Formulation [It consists of Gilo (*Tinospora cordifolia*) - 5 gm, Sad Kofi (*Cyperus rotundus*)-5 gm, Jatamansi (*Nardostachys Jatamansi*) - 7 and Berge Sena (*Cassia angustifolia*)-3 gm] was given at the dosages of 20 gm in the form of *Joshanda* (decoction) before food for the period of 28 days.

Subjective parameters (polyuria, polydipsia, polyphagia and tiredness) and objective parameters (fasting blood sugar, post prandial blood sugar) were carried out on pre and post (i.e. 0th and 30th days) study analysis. For this case series study; eight adult patients (5 males and 3 females) in the age group of 30-45 years with newly diagnosed cases.

Selection criteria include newly diagnosed cases of type 2 diabetes with Fasting Blood Sugar (FBS)>126 mg/dl, Post Prandial Blood Sugar (PPBS)>140 mg/dl, and aged between 30-45 years of either gender, patients willing to participate in the study and ready to follow the instructions. Exclusion criteria include pregnant, lactating women and other systemic disease.

The clinical efficacy was measured with subjective and objective parameters. All patients were followed up to assess response to treatment.

Table 1: Distribution of subjects by Gender, Numbers and Duration of Disease

S. No	Genders	No of Patients	Duration of Disease
1	Males	5	Newly Diagnosed
2	Female	3	Newly diagnosed

Table 2: Distribution of patients by Gender, Numbers and Duration of Disease

Parameters	Variables	Before Treatment (0 th Day)	After Treatment (28 th Day)
Subjective Parameters	Polyuria	Moderate	Nil
	Polydipsia	Mild	Nil
	Polyphagia	Mild	Nil
	Tiredness	Moderate	Mild
Objective* Parameters	FBS (mg/dl)	137	124
	PPBS(mg/dl)	165	147

Only average mean*

Result and Discussion

Diabetes Mellitus is a common metabolic and lifestyle disorder which affects both genders [8, 13] Currently prevalence of diabetes is highly escalating in India which may arise due to migration from rural areas to urbanization, sedentary lifestyle; altered food habits may increase the risk of obesity and diabetes [14]. Long term effect of diabetes leads to various complications viz., diabetic nephropathy, neuropathy, retinopathy, diabetic foot, and sexual dysfunction [8, 9] People with diabetes are at increased risk of cardiovascular, peripheral vascular and cerebrovascular diseases [10] Unani Medicine has great role to management of diabetes because which is based on multidimensional approach therapy (diet therapy, regimes and appropriate pharmacotherapy [8, 13]

Unani Formula which has been used for case series study in newly diagnosed cases of diabetes has found to be significant reduction in both subjective and objective parameters which is due to hypoglycemic effect. Most of the Unani drugs exhibits anti-diabetic activity, nootropic activity, antioxidant activity, immunomodulator activity [8, 13] Case series-Unani Formulation consists of *Gilo* - 5 gm, *Sad Kofi* - 5 gm, *Jatamansi* 7 and *Berge Sena* - 3 gm. Most of the ingredients of above formulation revealed anti-diabetic activity which was supported by Sangeetha MK (2013), Singh P (2015), Song MY (2010). Nambirajan G (2018) *et al.* [15-18]

Conclusion

Unani Formulation (It consists of *Gilo*-5 gm, *Sad Kofi*- 5 gm, *Jatamansi* -7 gm and *Berge Sena*- 3 gm) at the dosages of 20 gm in the form of *Joshanda* (decoction) before food for the period of 28 days has significant effect in newly diagnosed cases of diabetes. This case series study advocates that the Unani Formulation has potential effect to reduce subjective and objective parameters of diabetes. However, a long duration study with a larger sample size with standard control study is needed to further corroborate hidden pharmacological activities.

Acknowledged

Work is duly acknowledged to patients who are participated in this case series study.

Funding and Competing Interest: Nil

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