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Efficacy of Unani Formulation in the Management of Diabetes Mellitus Type 2: A Case Study

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bstract:

Diabetes Mellitus Type 2 (DMT2) is a chronic metabolic disorder characterized by insulin resistance and hyperglycaemia, leading to severe complications if left unmanaged. Conventional treatments include lifestyle modifications and pharmacotherapy, but alternative systems like Unani medicine offer promising therapeutic options. This case study evaluates the efficacy of a Unani pharmacopeial formulation (*Safoof-e-Ziabetes*) in managing DMT2 in a 62-year-old female patient with symptoms of polyuria, polydipsia, polyphagia, and lethargy. The formulation, comprising *Methi* (Trigonella foenum-graecum), *Tukm-e-Kalonji* (Nigella sativa), and *Tukm-e-Kasni* (Cichorium intybus), was administered at 3g twice daily for eight weeks alongside dietary modifications.

Significant reductions in Fasting Blood Sugar (FBS: 321 → 97 mg/dL) and Post-Prandial Blood Sugar (PPBS: 441 → 189 mg/dL) were observed, alongside symptomatic relief. The anti-diabetic, anti-hypertensive, and antioxidant properties of the ingredients likely contributed to these outcomes. Despite limitations, this study highlights the formulation's potential as an adjunct therapy for DMT2, warranting further large-scale trials to validate its efficacy and mechanisms. The findings suggest that Unani medicine may offer a viable complementary approach to improving glycaemic control and quality of life in diabetic patients.

Keywords: Unani medicine, Diabetes Mellitus Type 2, *Safoof-e-Ziabetes*, herbal formulation, glycaemic control, case study.

Introduction:

Diabetes Mellitus is a chronic disease that occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a medication that controls blood sugar. Hyperglycemia, also known as high blood sugar or high blood sugar, occurs when blood sugar levels are uncontrolled and can cause serious damage to many organs, especially arteries and veins, over time**.** Diabetes symptoms can strike without warning. The signs of type 2 diabetes might be subtle and take years to manifest**.** Symptoms of diabetes include feeling very thirsty (Polydipisa)**,** needing to urinate more often than usual (Polyuria), Excessive Hunger (Polyphagia), blurred vision, feeling tired, losing weight unintentionally. Over time, diabetes can damage blood vessels in the heart, eyes, kidneys and nerves. People with diabetes have

a higher risk of health problems including heart attack, stroke and kidney failure. Diabetes can cause permanent vision loss by damaging blood vessels in the eyes. Because Diabetes damages nerves and reduces blood flow, many patients with the disease experience foot difficulties. This may result in amputation and foot ulcers.

In 2014, 8.5% of adults aged 18 and over had diabetes. In 2019, diabetes caused 1.5 million deaths, 48% of which occurred before the age of 70. An additional 460,000 kidney disease deaths were due to diabetes, while diabetes accounts for about 20% of cardiovascular deaths. The death rate from diabetes is increasing by 13% in low- and middle-income countries. Between 2000 and 2019, the number of people aged 30 to 70 worldwide decreased by 22%.

Since 1980, the global agestandardized elderly rate has nearly doubled, from 4.7% to 8.5%. Approximately 72.9 million adults have diabetes. The state's high risk of diabetes reflects the country's prevalence. While locationspecific data may vary, studies show that the rate is generally higher in urban areas than in rural areas.[13]

Diabetes is divided into two types as Type 1 Diabetes and Type 2 Diabetes. Type 1 diabetes (previously known as insulin-dependent, juvenile or childhood-onset) is characterized by deficient insulin production and requires daily administration of insulin. In 2017 there were 9 million people with type 1 diabetes; the majority of them live in high-income countries. Neither its cause nor the means to prevent it are known.Type 2 diabetes affects how body uses glucose for energy. It prevents the body from using insulin properly, which can lead to high blood sugar levels if left untreated. Over time, type 2 diabetes can cause serious damage to the body, particularly to nerves and blood vessels. Being overweight, not exercising enough, and genetics are risk factors for type 2 diabetes; early diagnosis is crucial to preventing the worst effects of the disease. Type 2 diabetes symptoms can be mild and may take several years to manifest. Early diagnosis can be accomplished through relatively inexpensive testing of blood glucose. People with type 1 diabetes need insulin injections for survival. One of the most important ways to treat diabetes is to keep a healthy lifestyle. Some people with type 2 diabetes will need to take medicines to help manage their blood sugar levels. These can include insulin injections or other medicines. Some examples include metformin, sulfonylureas, sodium-glucose co-transporters type 2 (SGLT-2) inhibitors.

Along with medicines to lower blood sugar, people with diabetes often need medications to lower their blood pressure and statins to reduce the risk of complications.

Additional medical care may be needed to treat the effects of diabetes includes foot care to treat ulcers, screening and treatment for kidney disease, eye exams to screen for retinopathy (which causes blindness).

The most effective strategy to prevent or avoid type 2 diabetes is to modify one's lifestyle. In order to lessen the risk of type 2 diabetes and its consequences, people ought to achieve and maintain a healthy body mass. Maintain an active lifestyle by engaging in at least 30 minutes of moderate exercise every day. Prevent sugar and saturated fat by eating a balanced diet,refrain from using tobacco.

In Unani System of Medicine(USM) Diabetes mellitus is known as *Dhayābītus Shakri (DS)*. It is categorized under "*Amraz-i-Kulyā*" (renal illnesses) based on clinical manifestations including polyuria and

glycosuria.[1]According to *Jalinus* (Galen), the primary causes of this illness are deficiencies in the kidney's *quwwat-i-masika* (retentive faculty) and *quwwat-i-mughayyara* (transformative faculty). Numerous major Unani writings, including "*Al-Qanoon fi al-Tīb*" (Ibn Sina), "*Kamil al-Sanā*" (Ismail Jurjani), "*Kitab al-Ta'seer fi al-Madawa-al-Tadbeer*" (Ibn Zuhar), and "*Ikseer-i-Azam*" (Azam Khan), make reference to this illness[2-5.] According to Unani system of medicine, there are two varieties of Dhayābītus:

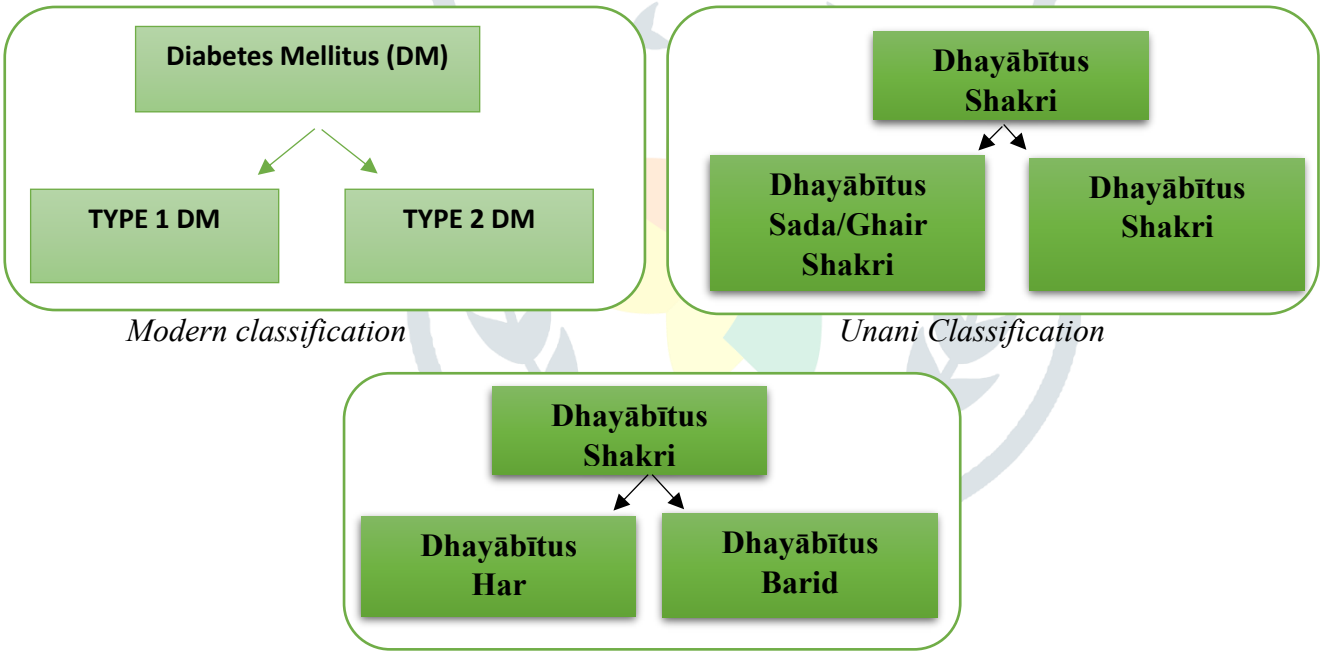
(i) *Dhayābītus Sada*, also called *Dhayābītus Ghair Shakri*, which is characterized by excessive thirst and polyuria without glycosuria, and

(ii) *Dhayābītus Shakri*, which is defined by polyuria with glycosuria and excessive thirst respectively.

Further, *Dhayābītus Shakri* is classified into two types according to the intensity and onset of the disease i.e.

(i) *Dhayābītus Hār* which is an acute type and characterised by polydipsia and polyuria. This type is mainly caused by *su-i-mizaj hār sada* (hot temperament without involvement of humour) of kidney and is manifested by excessive heat in the flanks and excessive dryness of the body.

(ii) *Dhayābītus Bārid* is considered as chronic type characterized by less intensity of polydipsia and polyuria[1,4,5.]



Modern classification

Unani Classification

Unani Classification according to Intensity and onset of disease

Many pharmacopoeial compound formulations such as

Table 1.1

Sufoof-i-Ziabetus	Sufoof-i-Sandal[6]	Sufoof-i-Hindi[8]
Qurs-i-Kafoor[5,6,7]	Qurs-i-Tabasheer[6,7]	Qurs-I Ziabetus Sada[10]
Sufoof-i-Sandal Ziabetus Wala[6,7,9]	Qurs-i-Ziabetus [5,6,7]	Qurs-i-Ziabetus Khas[10]
Arq-I Ziabetus [7]	Ma-us-Sha'eer[6]	Qurs-i-Gulnar[5,6]
Qurs-i-Tabasheer Kafoori[6]	Sufoof-i-Gilo[6]	

Qurs-i-Marjan[6]	Qurs-i-Marwareed[6]	

The compound formulations mentioned in Table 1.1 are some of the prescribed formulations for the treatment of Diabetes mellitus. A study has reported that a Unani pharmacopoeial formulation which contains *Samag-i-Arabi* (Acacia Arabica Willd. var. Indica Benth.), *Gulnar* (Punica granatum Linn.), *Damm al-Akhwain* (Pterocarpus marsupium Roxb.), *Shib-i-Yamani* (Almunium sulphate), *Badam* (Prunus amygdalus Baill.), and *Kateera* (Sterculia urens Roxb.) possess significant effect in cases of diabetic nephropathy as compared to control drug.[11] Another study has been carried out on 20 patients of Diabetes mellitus Type-2 for a period of 150 days in which a coded Unani formulation (UNIM- 210) showed a significant result[12]

Objective of study

The Main objective of this case study is to assess the efficacy of an Unani formulation in reducing the Fasting Blood Sugar & Post-Prandial Blood Sugar Levels and to produce improvement in the subjective parameters.

Methodology

In this study, a female patient, aged 62, visited our OPD (OPD number- U-4698), with complaints of intermittent Polyuria, Polydipsia, polyphagia and Generalised Lethargy since the past 6 months. The patient was apparently normal before 9 months and then she gradually developed the above-said symptoms. After three months the patient went for Blood Investigations and found Elevated Levels of Fasting Blood Sugar and Post-Prandial Blood Sugar. It is also to be noted that the patient has a family history of diabetes mellitus in First-Line.

The physical parameters and investigations were done and re-confirmed, of her, being Diabetic and the levels are mentioned in the baseline table.

The General Examination and history of Unani Diagnostic Parameters were recorded as follows: *Nabz* (pulse) of the patient was *Saree wa Mutwatir*, her *Bol* (urine) was increased, in Quantity and she also had complaints of Constipation.

Intervention and Analysis

After the assessment of Unani parameters viz., *Mizaj* of the patient and her disease, she was advised to take Unani Pharmacopeial preparation *Safoof-e-Ziabetes*, 3 grams, twice a day, with lukewarm water, before meal.

The patient was also advised to avoid sugar and Carbs-related diet, and advised to take *Saree- ul- Hazm* (Easily digestable) diet.

The ingredients of Unani Formulation(*Sufoof Ziabetes*) includes :

Name of the Drug	Scientific Name
Methi	*Trigonella foenum-graecum*
Tukm e Kalonji	*Nigella Sativum*
Tukm e Kasni	*Cichorium Intybus L.*

The ingredients of this formulation have been studied and standardised. They exibit anti-diabetic, anti-hypertensive, anti-microbial, anti-oxidant properties and are being used as potent herbs in many formulations in Unani System Of Medicine(USM) since many decades.

Evidence and Scientific Studies on Anti-Diabetic and other Medicinal Benefits of the ingredients of the Formulation:

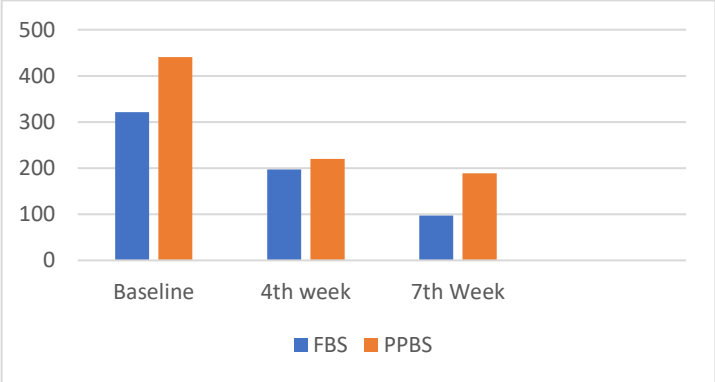
NAME OF THE DRUG	ACTIVITY	REFERENCE
Methi *(Trigonella foenum-graecum)*	Anti-Dyslipidemic	Ramulu P, Giridharan NV, Udayasekhararao P. Hypolipidemic effect of soluble dietary fiber (galactomannan) isolated from fenugreek seeds in WNIN (GR-Ob) obese rats. J Medicinal Plants Res 2011;5:4804- 4813.
	Hypoglycemic	Szabo K, Gesztelyi R, Lampe N, Kiss R, Remenyik J, Pesti-Asboth G, et al. Fenugreek (Trigonella foenumgraecum) seed flour and diosgenin
		Li G, Luan G, He Y, Tie F, Wang Z, Suo Y, Ma C, Wang H. Polyphenol stilbenes from fenugreek (Trigonella foenum graecum L) seeds improve insulin sensitivity and mitochondrial function in 3T3-L1 adipocytes. Oxid. Med. Cell Longev.e Collection 2018, 1-9. doi: 10.1155/2018/7634362.
	Anti-Cancer	Sebens S, Bauer I, Geismann C, Griebenow EG, Ehlers S, Kruse ML et al. Inflammatory macrophages induceNrf2 transcription factor-dependent proteasome activity in colonic NCM460 cells and thereby confer antiapoptotic protection. J Biol. Chem 2011;286:40911- 40921.
	Anti-Bacterial	Sharma V, Singh P, Rani A. Antimicrobial activity of Trigonella foenum-graecum L. (Fenugreek). Eur. Exp. Biol 2017;7:1-4.

	Anti-Hypertensive	Hamden K, Keskes H, Belhaj S, Mnafgui K, Feki A, Allouche N. Inhibitory potential of omega-3 fatty and fenugreek essential oil on key enzymes of carbohydratedigestion and hypertension in diabetes rats. Lipids Health Dis. 2011;10:226. doi: 10.1186/1476-511X-10-226.
Tukm e Kalonji *(Nigella Sativum)*	Anti-Dyslipidemic	Rasheed A, Siddiqui MA, Khan JA. Therapeutic evaluation of Kalonji (Nigella sativa) in dyslipidemia. A Randomized control trial. Medical Journal of Islamic World Academy of Sciences. 2014;22(3):111-116.
	Hypoglycemic	Alam S, Reddy SK, Baig A, et al. Evaluation of anti-diabetic and anti-lipidimic potential of kalongi sugar powder water extract in Streptozocin induced diabetic rats. International Journal of Pharmacy and Pharmaceutical Sciences. 2013;5(1):94-96
	Anti-Cancer	Raval BP, Shah TG, Patel JD, et al. Potent anticancer activity of Nigella Sativa Seeds. Archives of Applied Science Research. 2010;2(1):52-56
	Anti-Bacterial	Hannan A, Saleem S, Chaudhary S, et al. 2008. Anti-bacterial activity of Nigella sativa against clinical isolates of methicillin resistant Staphylococcus aureus. J Ayub Med Coll Abbottabad. 2008;20(3):72-74.
	Nephroprotective	Hikmah Z, Endaryanto A, Ugrasena ID, et al. Nigella sativa L. as immunomodulator and preventive effect on renal tissue damage of lupus mice induced by pristane. Heliyon. 2022; 8(4):1-9. https://doi.org/10.1016/j.heliyon.2022.e09242.
Tukm e Kasni *(Cichorium Intybus L.)*	Anti-Diabetic/ Hypoglycemic	Anju , Javed G, Javaid R, Ahmed F. Kasni (Cichorium intybus): A Unani Hepatoprotective Drug. JDDT [Internet]. 15Jul.2020 [cited 26Sep.2024];10(4):238-41. Available from: https://jddtonline.info/index.php/jddt/article/view/4162
	Anti-Tumour	Angelina Quintero Araceli, Pelcastre and Dolores Jose, Antitumoral of Pyrimidinederivatives of Phytochemical sesquiterpen lactones. J Pharm. Pharmaceut. Sci., 1999, 3: 108-112.
	Anti-Cancer	Hazra B., Sarkar R., Bhattacharyya S. and Roy P., Tumour inhibitory activity of chicory root extract against Ehrlich ascites carcinoma in mice, Fitoterapia, 2002, 73: 730-733.

	Anti-Bacterial	Bischoff TA, Nguyen-Dinh P, AG, Arefi M, Laurantos CJ, Kelley and Y. Karche sy, Antimalarial activity of Lactucin and Lactucopicrin sesquiterpene lactones isolated from Cichorium intybus L. J. Ethnopharmacol, 2004; 95, 455- 457.

The assessment of symptoms was recorded in each visit and the laboratory investigation (i.e., Fasting and Post-Prandial Blood Sugar Levels) were recorded at baseline, 4th and 8th week from baseline.

PARAMETERS	BASELINE	4thWEEK	7th WEEK
Fasting Blood Sugar(mg/dl)	321	197	97
Post-Prandial Blood Sugar(mg/dl)	441	220	189



Results

The patient was followed up at regular intervals and had been strictly kept on the above said diet. Results in the 4rd and 7th week when compared to the baseline clearly shows the drastic difference in the parameters, especially the marked reduction of Fasting Blood Sugar (FBS) level of about 144 mg/dl (321 : 236 : 97) and Post-Prandial Blood Sugar of about 120 mg /dl(217 : 150 : 97) within a treatment period of 7-8 weeks.

The patient also improved subjectively with her above-mentioned symptoms in the subsequent visits.

It is certainly evident from the literature that the results obtained are due to the various medicinal properties of the ingredients of this Unani Formulation.

Discussion

The present study proves the effectiveness of the Unani Formulation in the reduction and maintenance of blood glucose levels in Diabetes Mellitus (DM). Though a significant difference is observed in this study, it has a lot of limitations and must be checked out for the internal and external validity by carrying out further higher studies on it to confirm its exact effectiveness.

Conclusion and recommendation

Thus, it can be concluded that, this case demonstrates that the Unani Formulation proves to be an effective and potent medication in reducing Fasting Blood Sugar(FBS) and Post-prandial Blood Sugar(PPBS) Levels and helpful in patients with hypertension, dyslipidaemia, etc., thereby contributing as a potent drug in combating Metabolic disorders.

Thus, the formulation helps in improving the overall Quality of Life in patients with Metabolic Disorders, especially Diabetes Mellitus and through further higher studies, could further contribute as an alternate or adjuvant to the wide population affected by the disease.

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