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## Research Article

# Evaluation of Anti-Diabetic Effects of “Qurs-E-Ziabetes”: A Polyherbal Unani Preparation in Type 2 Diabetes Mellitus

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### Abstract

Qurs-e-Ziabetes (QZ) is a polyherbal Unani preparation for type 2 diabetes mellitus (T2DM). The present study was carried out for the clinical evaluation of the anti-diabetic effects of QZ. The study was conducted in 40 patients after the Institutional Ethical Committee approval and taking written informed consent. Two groups were followed up weekly for four weeks in a variable dose clinical study after diagnoses of Diabetes Mellitus. Group - 1 was given two tablets of QZ 250 mg each twice a day 30 minutes before breakfast and dinner respectively. Group - 2 received three tablets twice a day in the same manner. Thirty patients were enrolled in group - 1 and ten patients in group - 2 after clearing inclusion and exclusion criteria. The study involved 52% male patients and 48% females with the mean age of 48.54± 11.98 years. Out of them 74 % were of Balghami temperament (Sedentary life-style). The mean chronicity of the disease was 16.62±12.78 years. The patients in both the groups (Group - 1 and Group - 2) showed statistically significant reduction in blood sugar levels from baseline to the end of four weeks with a P value of < 0.001. The baseline values of sugar levels 192.73±43.65 mg/dl fasting and 283.97±73.68 mg/dl post-prandial reduced to 112.5±17.45 mg/dl fasting and 143.63±25.44 mg/dl post-prandial respectively in group - 1 and from 186.9±33.31 mg/dl fasting and 291.8±35.19 mg/dl post-prandial to 98.6±13.10 mg/dl fasting and 131.8±23.58 mg/dl post-prandial respectively in Group - 2. The QZ was found to have excellent response with highly statistically significant therapeutic effects in T2DM with respect to lowering blood sugar levels as well as clinical improvement.

### 1. INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disorder characterised by the hyperglycaemia, polyuria and polydipsia which has now attained a pandemic proportion in the human society irrespective of the race, religion, socioeconomic profile and geographic location in the world. The numbers of people suffering from this disorder are increasing in the world so much so that it would share 11.6% of the total international expenses on healthcare in 2010 and cost would escalate up to the \$490 billion by 2030<sup>1</sup>.

The Asian developing countries including India have shown rise in its prevalence<sup>2</sup>. The India has become the world capital of Diabetes Mellitus<sup>3</sup>. Various studies have shown the association of type 2 Diabetes Mellitus (T2DM) with the sedentary life style what is called as Balghami temperament in Unani medicine<sup>4</sup>.

The DM is divided into the Insulin Dependent Diabetes Mellitus (IDDM) and Non-Insulin Dependent Diabetes Mellitus (NIDDM). The former category of patients entirely depends on the exogenous supply of insulin because of the extensive damage to the insulin producing  $\beta$  cells of pancreas. And the latter is characterised by the decrease insulin sensitivity and treated with diet control, exercise and pharmacotherapy. Although exact aetiology of this condition has not yet been understood correctly but many studies point towards the free radicals involvement in pathogenesis and diabetic complications<sup>5-7</sup>.

Free radicals are reactive molecular species which causes destruction of the cellular structures including proteins, lipids and genetic material. The abnormalities in functional aspect of affected cells lead to the development of the complications. The free radical oxidation of lipoproteins such as LDL, VLDL and HDL causes cardiovascular complication while spontaneous oxidation of the structural glycoproteins through non-enzymatic glycosylation leads to the advancement of the insulin resistance and destruction of the pancreatic cells<sup>8</sup>. The diabetic state leads to the tremendous generation of free radicals and decrease in levels of antioxidants<sup>9-12</sup>. Although studies have shown natural protective role of antioxidants such as Vitamin C and E present in the diet. However large numbers of plants have also shown antioxidant mechanism of their effects in various diseases including diabetes<sup>13-14</sup>.

Therefore herbal based drugs are being prescribed for their regional availability, affordable cost, less adverse effects and comparable effectiveness<sup>15</sup>. There is large demand of natural and alternative medicinal products in the global market along with the synthetic modern day medicine. A large number of plants with different mechanism of action have been identified for their anti-diabetic potential such as *Allium sativa*, *Eugenia jambolana*, *Gymnema sylvestre*, *Momordica charantia*, *Phyllanthus amarus*, *Pterocarpus marsupium* and *Trigonella foenum graecum*<sup>16</sup>. Numerous physicians of modern system of medicine are prescribing natural compounds containing flavonoids for their antioxidant potential<sup>17</sup>. Furthermore oxidative stress has a great role in damaging the insulin producing cells of pancreas and diabetic complications in diabetes mellitus<sup>18</sup>.

As DM is a multifactorial complex metabolic disorder. The role of medicines of the alternative system of medicines including Unani system of medicine in modern healthcare set-up needs a clinical validation for optimizing their therapeutic potential. This study was

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carried out to evaluate the anti-diabetic effects of a polyherbal Unani preparation called "Qurs-e-Ziabetes" in patients of T2DM.

**2. MATERIALS AND METHODS**

The subjects for the variable dose clinical study were selected from the OPD of the Majeedia Hospital, Jamia Hamdard, New Delhi. A total of 40 patients were enrolled. The cases were first screened for clinical examinations. The patients with less than five years chronicity and free from any other systemic complication were selected for the study. The pregnant women and children were excluded from the study. In this study only NIDDM (T2DM) patients were included. Those having signs and symptoms of Diabetes Mellitus (Ziabetes Shakkri) were referred for urine examination and blood sugar levels in the investigations. Those found positive and fulfilling the above mentioned criteria were selected for the study. Others investigations like Kidney Function Test, Liver Function Test, X-ray chest and Electrocardiogram (E.C.G) were carried out to ruled out any other complications. Institutional Ethics Committee approval for the study and a written informed consent of the patient was obtained before registering them in the present study. On admission the cases were subjected to thorough clinical examination and pathological and biochemical investigations and the findings were recorded in the Case Record Form (CRF) devised for the purpose of the study.

The QZ was obtained from Hamdard Dawakhana, Delhi as per its pharmacopeia. The few of the ingredients of the drugs were revealed to carry out this clinical study. The patients were allocated to one of the two treatment groups. In group - 1, the drug was given in the dose of two tablets 250 mg each 30 minutes before breakfast and 30 minutes before dinner i.e., twice daily. Whereas in group - 2 the patients were given three tablets twice daily as in group - 1. The patients were followed weekly for the four weeks. At each follow up all the clinical signs and symptoms were recorded and urine examinations and blood sugar level investigations were repeated and recorded properly in the follow up sheets. The patients were advised to follow the recommended diet schedule during the treatment period.

The criteria for clinical assessment for response of the therapy was classified as Excellent Response (ER) if there is complete subsidence in different signs and symptoms along with normalisation of the blood sugar levels. It was categorised as Good Response (GR) if patients showed complete subsidence in different signs and symptoms along with reduction in the blood sugar levels near to border line. However Poor Response (PR) patients were those who showed subsidence in some of the signs and symptoms with no reduction in the blood sugar levels.

**3. RESULTS AND DISCUSSION**

Out of the 40 patients selected for the study, 52% were male and 48% female. The mean age was 48.54±11.98 years. The 74% of the patients were of Balghami temperament (sedentary life-style). The anthropometric data at the baseline such as the average weight, average height and BMI was taken which was found to be 61.68±8.82 Kg, 152±0.10 cms and 26.17±5.34 respectively. The various signs and symptoms of Diabetes Mellitus (a.k.a Ziabetes Shakkri in Unani) were present in most of the cases. The presence of these symptoms differed according to the chronicity of the disease. The symptoms such as polyuria, polyphagia, polydipsia, tiredness, loss of libido, muscle cramps and constipation were present in majority of the patients. However numbness, neuritis and skin infections have also been observed in some chronic cases. Thirty patients were studied in group - 1. These patients were given the drug in the dose of two tablets (250 mg) 30 minutes before breakfast and 30 minutes before dinner for a period of four weeks. The signs and symptoms in these patients were reduced significantly. The effects of the drugs on the symptoms such as polyuria, polydipsia, polyphagia, tiredness, itching, giddiness, insomnia and constipation were statistically significant. There was statistical significant (P < 0.001) reduction in both fasting and postprandial blood sugar levels. These reductions were consistent as evident from the data of weekly investigations of blood sugar levels. This reduction was found to be statistically significant when compared with the base line blood sugar levels (Table - 1).

**Table 1:** Reduction in Blood sugar levels before and after the treatment in Group – 1

Blood Sugar Levels	No. of patients	Base line (Mean±S.D)	After 4 weeks (Mean ±S.D)	t-Statistics	t-table value	Significance
Fasting	30	192.73±43.65	112.5±17.45	9.56	2.05	P < 0.001
Postprandial	30	283.97±73.68	143.63±25.44	11.60	2.05	P < 0.001

Ten patients were studied in group - 2. The drug was given in the dose of three tablets 30 minutes before breakfast and 30 minutes before dinner. The treatment was given for a period of four weeks. Various signs and symptoms in these patients were also reduced significantly. Patients with the symptoms of numbness and neuritis

also responded well as compared to group – 1. The reduction in both the fasting (FF) and postprandial (PP) blood sugar levels were statistically significant (P < 0.001) (Table - 2). Similar to group – 1 the fall in the blood sugar levels was consistent as evident from the data of weekly follow –ups.

**Table 2:** Reduction in Blood sugar levels before and after the treatment in Group - 2

Blood Sugar Levels	No. of patients	Base line (Mean±S.D)	After 4 weeks (Mean ±S.D)	t-Statistics	t-table value	Significance
Fasting	10	186.90±33.31	98.6±13.10	11.59	2.26	P < 0.001
Postprandial	10	291.80±35.19	131.80±23.58	27.60	2.26	P < 0.001

While comparing the response in group - 1 and 2, it has been noted that the reduction in the blood sugar levels was much more significant in group - 2. That may be attributed due to the intake of the higher dose. In group – 1, twenty (66.6%) patients showed excellent response, eight (26.6%) showed good response and two (6.6%) showed poor response. In group - 2 eight (80%) patients showed excellent response, one (10%) showed good response and one (10%) patients showed poor response (Table - 3).

Our study findings are in consistent with the other studies which has resulted the advent in a paradigm shift in last decade from synthetic to natural methods of treatments<sup>19-22</sup>. The Unani system of medicine offers natural therapeutic agents which were either used singly or compounded. The QZ is a combination of various drugs from plants, animals and mineral origin. Some of them are Hammaz, Binola, Hartal, Gul-e-Surkh, Gulmar buti, etc. which were known as traditional hypoglycemic/anti-diabetic medicinal agents used since centuries.

Despite being a coded drug some of the ingredients of QZ were revealed. Some of them have already been reported of anti-diabetic activities in scientific research. Although herbal compounds in this preparation such as Hammaz (*Rumex vesicarius*), Binola (*Gossypium herbaceum*), Gulmar buti (*Gymnema sylvester*) needs further validation. However some of the plants have substantive evidence of their anti-diabetic potential such as Gul-e-surkh (*Rosa damascena*) extracts have shown intensive non-competitive

**Table 3:** General therapeutic response outcome

Category	Excellent	Good	Poor
Group – 1	20 (66.6%)	8(26.6%)	2(6.6%)
Group – 2	8(80.0%)	1(10.0%)	1(10.0%)

inhibition of alpha glucosidase enzyme resulting in reduction of postprandial carbohydrate absorption<sup>23</sup>. Barg-e-kasni (*Cichorium intybus*) have shown a decline in hepatic glucose-6-phosphatase (Glc-6-Pase) activity without any change in serum insulin levels in animal studies. Thus it results in lower blood glucose concentration due to decrease hepatic glucose production in short-term as well as long-term diabetic condition delaying its onset and progression<sup>24-25</sup>. Neem (*Azadirachta indica*) has shown the anti-diabetic/hypoglycemic effectiveness in clinical<sup>26</sup> as well as animal studies<sup>27</sup> where it not only delays the onset but also prevents the progression of DM. The phytochemical and pharmacological studies of these plants showed that these plants exerted anti-diabetic/hypoglycemic activities in rats. Therefore the decade long use of QZ as anti-diabetic by Unani physicians occupies a scientific justification. As it is always a problem with Unani drugs poly-formulations that it cannot be established that which of the drug exerts more corrective effects than other but it might be justifiable on the ground that combinations of various drugs in Unani system might be for synergism, antagonising, and detoxifying effects for the ingredients. Forty patients of either sex who had history of NIDDM were selected for the clinical evaluation of the QZ in this study. The patients of 30-70 age of either sex having no serious complications were found to have good response. Some of them showed excellent response. The QZ has brought down their symptoms of itching and other troubling symptoms. In addition to that it was a critical issue of less percentage of sufferers from non-vegetarian habits. It could be matter of further research. The association of disease was found to be common in Balghami temperament. That may be established that less physical work and luxurious life style contributes to the much of the onset of disease. During the course of the study of four weeks, the effects of QZ on fasting and postprandial blood sugar found to be statistically significant. Besides the lowering down of the blood sugar in FF and PP conditions, the test drug also exerted a very positive effect on the overall symptomatology and improved the well-being of the patients. Therefore it is found that QZ has a rational basis of its use as anti-diabetic/ hypoglycaemic activity.

After completion of the four weeks treatment the data were analysed and results evaluated. The significant therapeutic effects of this formulation have been observed in subsiding different signs and symptoms as well as normalising the blood sugar levels. Thus the drug QZ has shown significant anti-diabetic and hypoglycaemic effects. Since the study was on a very limited sample size, further studies on large sample size may produce more substantive findings.

#### 4. CONCLUSION

In conclusion, the data of this clinical study validate the old age Unani polyherbal formulation for the treatment of type 2 diabetes mellitus. The drug "Qurs-e-Ziabetes" not only reduces the fasting as well as postprandial blood sugar levels but also improve the overall clinical symptomatology of the patients. The different dosage regimens in the two groups of this study also open the avenues for further clinical studies for standardisation of the therapy involving three tablets of 250 mg each twice a day. The outcome measures of further research may include the compliance, adverse outcomes and long term control of blood sugar levels with the larger sample size.

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