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Dr. Majid Ali Ansari
PG Scholar, Department of Moalijat, A & U Tibbia College, Karol Bagh, New Delhi, Delhi, India

Rais-Ur-Rahman
HOD Moalijat, A & U Tibbia College, Karol Bagh, New Delhi, Delhi, India

Corresponding Author:
Dr. Majid Ali Ansari
PG Scholar, Department of Moalijat, A & U Tibbia College, Karol Bagh, New Delhi, Delhi, India

A clinical study on ziabetus shakri qism doem (Diabetes mellitus type 2) and its management with Unani formulation, a randomized standard controlled study

Dr. Majid Ali Ansari and Rais-Ur-Rahman

Abstract
The word "Diabetes" is derived from the Greek word "Diabanmo", which means passing through or to run through or siphon. According to Unani literature retrieved from Al Qaanon, Al Hawi, Kamilus Sanaah, diabetes mellitus is called Ziabetus Sakri. The description of ziabetus (Diabetes) in Unani classical literature is available since the time of Hippocrates and Ziabetus was considered as a disease of the kidneys. Arabian physicians have also described Ziabetus by the terms: Moattasha/Atsha, Zalaqul kulliya, Dolab, Dawwarah, Barkar/Barkarya, and Qaramees. Type 2 Diabetes Mellitus is a heterogeneous group of disorders characterized by variable degree of insulin resistance, impaired insulin secretion and excessive hepatic glucose production. Common presenting symptoms of Diabetes Mellitus include polyuria, polydipsia, polyphagia, weight loss, fatigue, weakness, blurred vision, frequent superficial infections and poor wound healing. The chronic hyperglycemia of diabetes is associated with long term complications, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels. In conventional system of medicine several classes of drugs are being used to manage Type 2 Diabetes Mellitus, but apart from being effective, most of these drugs have drastic side effects on several organs and body functions, hence, their long term use is not in favour of the wellbeing of the Diabetic patient. In order to overcome the problem of the unwanted effects of the modern drugs, a clinical study with a Unani polyherbal formulation containing Shoneez (Nigella Sativa), Darchini (Cinnamon zeylanicum), Hulba (Trigonella foenum graceum) and Maghz Tukhm-e-Jamun (Syzygium Cuminum) for the management of Diabetes Mellitus Type 2 has been undertaken. At the end of the study the test drug was found efficacious and safe in the treatment of Type 2 Diabetes Mellitus.

Keywords: Diabetes mellitus type 2, Ziabetus Shakri Qism Doem, Shoneez, Maghz Tukhm-e-Jamun, Hulba, Darchini

Introduction
Diabetes Mellitus comprises a group of metabolic disorders that share the common feature of hyperglycemia [1]. As per the American Diabetic Association, diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both [5].

There are two broad categories of DM, designated as type 1 & type 2. Type 1 DM is characterized by absolute insulin deficiency and a tendency to develop ketosis, whereas Type 2 DM is a heterogeneous group of disorders characterized by variable degree of insulin resistance, impaired insulin secretion and excessive hepatic glucose production. Usual presenting clinical features of Diabetes Mellitus include polyuria, polydipsia, polyphagia, weight loss, fatigue, weakness, blurred vision, frequent superficial infections and poor wound healing [1]. The chronic hyperglycaemia in diabetes is associated with long term complications, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels [5]. Owing to its complications, it is a leading cause of morbidity and mortality despite of advancement of modern science.

The word "Diabetes" is derived from the Greek (Unani) word "Diabanmo", which means passing through or to run through or siphon. According to Unani literature retrieved from Al Qaanon, Al Hawi, Kamilus Sanaah, diabetes mellitus is called Ziabetus Sakri. The description of ziabetus (Diabetes) in unani classical literature is available since the time of Hippocrates and Ziabetus is considered as a disease of the kidneys. Arabian physicians have also described Ziabetus by the terms: Moattasha/Atsha, Zalaqul kulliya, Dolab, Dawwarah, Barkar/Barkarya, and Qaramees [12-16].

The comprehensive management of DM requires lifestyle modification (dietotherapy & exercise) especially on the principles of Asbab e Sitta e Zarooriya (6 essential factors) and pharmacotherapy. However, in many cases merely lifestyle management may not be sufficiently effective in treating the disease.

Diabetes Mellitus is an important worldwide public health problem. The global increase in the prevalence of diabetes is due to urbanization, an increase of obesity and physical inactivity [2]. Type 2 Diabetes Mellitus is the most common type of diabetes accounting for 85% to 90% of the cases [3]. Diabetes is one of the largest global health emergencies of the 21stcentury. In 2020, according to International Diabetes Federation, 463 million people have diabetes in the world. India has an estimated 77 million people with diabetes which makes it the second most affected in the world after China [25]. Classically, the age of onset of Type 2 Diabetes is above 40 years. However, in Indians it has been found to be a decade earlier than in the west. Obesity is not a common feature in Type 2 Diabetes in India. Only about 50% of cases have a BMI > 25 kg/m2 while, 15-20% of the patients are underweight. Approximately 4.0 (3.2-5.0) million people aged between 20-79 years are estimated to die from diabetes in 2017, which is equivalent to one death every 8 seconds [10].

DM has a substantial economic impact on countries and National Health systems. Most of the countries spend between 5% - 20% of their total health expenditure on diabetes. This is because of an increase in use of health services, loss of productivity and the long term support needed to overcome its complication, with such a high cost, the disease is a significant challenge for healthcare systems and an obstacle to sustainable economic development [11, 12].

Several group of anti-diabetic agents (sulfonylurea, biguanide, DPP4 & SGLT2 inhibitors and insulin analogue etc.) are already being used but long term use of these drugs results in development of various side effects like Hypoglycemic episodes, aplastic anaemia and haemolytic anaemia, diarrhoea, nausea and lactic acidosis etc.

Owing to prevalence and dreadful complications of Diabetes Mellitus and lack of relatively safe and effective drug for its management, search for better and safe cost effective therapeutic agent has been thrust area for research, in every field of medical science.

Unani scholars have also described many safe and effective single and compound anti diabetic drugs in Classical Unani Literature and they are being used for the treatment of Diabetes Mellitus for very long period but these medications have not been evaluated on scientific parameters for their effectiveness and side effects so far.

Keeping in view the above factors, present study have been designed to evaluate the safety and efficacy of a Unani Polyherbal formulation in the treatment of Type 2 Diabetes Mellitus.

Materials and Methods

The present clinical trial entitled as "A Clinical Study on Ziabetus Shakri Qism Doem (Diabetes Mellitus Type 2) and Its Management with Unani Formulation, A Randomized Standard Controlled Study" has been undertaken in the department of Moalijat, Ayurvedic and Unani Tibbia College and Hospital Karol Bagh, New Delhi. The patients were selected from the same hospital for the assessment of the safety and efficacy of test drug. Before starting the trial, the research protocol was submitted for ethical clearance. The Institutional Ethics Committee of A & U Tibbia College Karol Bagh, New Delhi has approved the protocol for the study. Individually every patient of DM type 2 was thoroughly questioned for detailed history of the disease. Patients were clinically examined and subjected to required hematological and biochemical investigations. Clinical signs, symptoms and investigations were recorded on the prescribed case record form, designed for the study under the direct supervision of supervisor.

Objectives of Research

- To evaluate the safety and efficacy of the Unani formulation in reducing blood sugar by using Modern Parameters.
- To provide safe and cost effective drug for the Management of Diabetes Mellitus.
- To evaluate the efficacy of Test drug in comparison to a standard hypoglycemic drug.

Inclusion criteria

- Fasting Blood Sugar ≥ 126 mg / dl
- Random Blood sugar ≥ 200 mg/dl
- HbA1c ≥ 6.5%
- Patients between the age group of 18 to 65 years.
- Patient of either sex, i.e. male, female or transgender.
- Patient ready to participate in the study and ready to follow the instructions.

Exclusion criteria

- Anaemia (HB % <8 gm % in females and <10 gm % in males)
- Patients of less than 18 years or more than 65 years of age.
- Pregnant and lactating women.
- Hepatic and renal disorder.
- Patients with cardiovascular disorders (uncontrolled HTN and CAD)
- Patients with uncontrolled infection (TB, UTI, etc.)
- Patient suffering from Diabetes Insipid us, Diabetes Mellitus Type 1.

Study design

The study was designed as a randomized standard controlled study.

Randomization

Sixty patients were randomly allocated by using lottery method into two groups, comprising 30 patients in each of test group and control group respectively.

Sample size

Sample size was fixed as 60 patients.

Duration of protocol therapy

The treatment period in both test and control groups was fixed as 56 days.

Dosage schedule

The Test group received powdered form of Unani formulation in the dose of 5grams orally twice daily with plain water for 56 days.

The control drug Metformin (Glycimet) one tablet of 500 mg was administered orally twice daily with plain water for

56 days to the patients of control group.

Justification for selecting the Unani formulation

Diabetes is a disease of cold temperament (Sue Mizaj Barid) especially of liver and kidney. The temperament of trial Polyherbal Unani formulation is estimated as Hot & Dry. As per the principles of Ilaj Biz Zid the Polyherbal formulation of hot and dry temperament would be successful in treating the diabetes mellitus. Furthermore, every single ingredient of the trial drug have been reported to possess anti diabetic property that is helpful in significant reduction in blood sugar level & symptoms of diabetes i.e. polyuria, polydipsia & polyphagia. In addition to this, these drugs have been reported to possess Musaffiyat e dam (Blood purifier) hypolipidemic and antioxidant properties, Nervine tonic and weight reducing actions that could also be helpful in reducing blood sugar and managing the complications.

Method of preparation of study drugs

The crude drugs namely Kalonji (Nigella Sativa), Darchini (Cinnamon zeylanicum), Methi (Trigonella foenum graceum) and Maghz Tukhm-e-Jamun (Syzygium Cuminum) were procured from the local market and botanical identity of the drugs was certified from CSIR-NISCAIR (National Institute of science communication and information resources), New Delhi. Each of the above drugs were then converted into powder form. Equal proportion of each powdered drugs were mixed together to make the trial drug for the study.

The control drug Metformin 500 mg (Tablet Glycimet 500 mg) was procured from the market.

Study procedure

Screening of the patients was done one week prior to the onset of the study. During the screening procedure the volunteers were properly interrogated, thoroughly examined physically, investigated on haematological and biochemical parameters for making the diagnosis.

Informed consent

Patients fulfilling the inclusion criteria mentioned above were informed and they were made understand all about the study, investigations to be carried out, the drug to be used, method of treatment and they were further asked to sign the informed consent form.

Parameters for the evaluation of efficacy of trial drugs in the treatment

To assess the response of treatment, the following subjective and objective parameters were used in the study.

Subjective parameters

1. Polyuria
2. Polydipsia
3. Polyphagia
4. Tiredness
5. Nocturia
6. Numbness
7. Cramps
8. Burning in palms / soles.

A Numeric rating Scale for the above symptoms was made as under for the feasibility of assessment of each symptom.

No Symptom 0
Mild Symptom 1

These symptoms are mild and there is no disturbances in his daily routine work. Moderate Symptom 2
These symptoms are not severe but there is disturbances in his daily routine work for some extent.
Severe Symptom 3
These symptoms are severe and patient could not perform his daily routine work.

Objective parameters

Recording of Fasting & Post Prandial Blood sugar were recorded at the base line and later on at 14 days intervals.

Investigations

The laboratory investigations such as Hemogram, liver function test, kidney function test, lipid profile, blood sugar fasting and post prandial were carried out at base line and at the end of treatment for assessment of safety and efficacy of the test drug.

Assessment of temperament (Mizaj)

Determination of Mizaj (temperament) was done on the basis of ten classical parameters (Ajnas-e-Ashra) as prescribed in classical Unani literature.

Table: Assessment of Mizaj (temperament)

Parameters	Damwi (sanguine)	Balghami (Phlegmatic)	Safravi (Bilious)	Saudavi (Malencholic)
Complexion	Reddy (reddish)	Chalky (whitish)	Pale (yellowish)	Purple (blackish)
Built	Muscular & broad	Fatty & broad	Muscular & thin	Skeletal
Touch	Hot & soft	Cold & soft	Hot & dry	Cold & dry
Hair	Black & lusty thick, rapid growth	Black & thin slow growth	Brown & thin rapid growth	Brown & thin Slow growth
Movement	Active	dull	Hyper active	Less active
Diet (Most suitable)	Cold & dry	Hot & dry	Cold & moist	Hot & moist
Weather (Most suitable)	Spring	Summer	Winter	Autumn
Sleep	Normal	In excess	Inadequate	Insomnia
Pulse	Normal 70 – 80 / min	Slow 60 – 70/ min	Rapid 80 – 100/ min	Slow 60 – 70/ min
Emotions	Normal	Calm & Quiet	Angry	Nervous

Distribution of Patients According to Temperament

During the course of study, patients were divided into four groups according to temperament. It was observed that the incidence of sanguineous (Damvi), Bilious (Safravi), Phlegmatic (Balghami) and Melancholic (Saudavi) temperament were 23 cases, 09 cases, 27cases and 1 case respectively.

Table 1: Distribution of Patients According to Temperament

Type of Temperament	No. of Males (%age)	No. of Females(%age)	Total no. of patients	Percentage
Damvi (Sanguineous)	17 (28.33%)	6 (10%)	23	38.34%
Safravi (Bilious)	2 (3.33%)	7 (11.67%)	9	15%
Balghami (Phlegmatic)	13 (21.66%)	14 (23.33%)	27	45%
Saudawi (Melancholic)	0	1 (1.66%)	1	1.66%
Total	32 (53.33%)	28 (46.66%)	60	100%

Adverse / Side effects

No side effects were reported by the patient during the course of clinical study.

Statistical analysis

After eight weeks of the treatment, the pre-treatment and post-treatment values of subjective and objective parameters of each group were analyzed statistically to evaluate the efficacy of the treatment by applying appropriate statistical tests.

Concomitant medication

All the Patients were advised that neither they should participate in any other study concomitantly nor to take any other drug without informing the investigator.

Observations and Results

Effects of the trial drugs were observed in both the groups which are as under

Effect of Trial drugs on Blood sugar fasting in the study

In the test group the mean Blood sugar fasting was 161.93 at the base line which got reduced to 122.03 at the end of the treatment. The effect of the drug was found highly significant (t = 9.038, p = 0.0001). There was 24.64% reduction in fasting blood sugar.

In the control group the mean Blood sugar fasting was 217.33 at the base line which got reduced to 155.53 at the end of the treatment. The effect of the drug was found highly significant (t = 7.642, p = 0.0001). There was 28.43% reduction in fasting blood sugar.

Effect of Trial drugs on Blood sugar post prandial in the study

In the test group the mean Blood sugar post prandial was 239.93 which got reduced to 177.8 at the end of the treatment. On applying paired 't' test the effect of the drug was found highly significant (t = 10.592, p = 0.0001). There was 25.89% reduction in post prandial blood sugar.

In the control group the mean Blood sugar post prandial was 332.46 at the beginning of the study which got reduced to 228 at the end of the treatment. The effect of the drug was found highly significant (t =13.795, p = 0.0001). There was 31.42% reduction in post prandial blood sugar.

Table 2: Intergroup Comparison of Test group vs Control group on Blood sugar fasting and post prandial

Blood Sugar		Mean mg/dL 0 Day	Mean mg/dL 56th Day	% Change	t Value	P Value	Statistical Result
Blood sugar fasting	Test Drug	161.93 ± 4.84	122.03 ± 5.34	24.64	9.038	0.0001	Highly Significant
	Control Drug	217.33 ± 10.44	155.53± 10.77	28.43	7.642	0.001	Very Significant
Blood sugar post prandial	Test Drug	239.93 ± 9.52	177.8 ± 10.84	25.89	10.592	0.0001	Highly Significant
	Control Drug	332.46 ± 14.40	228 ± 14.12	31.42	13.795	0.0001	Highly Significant

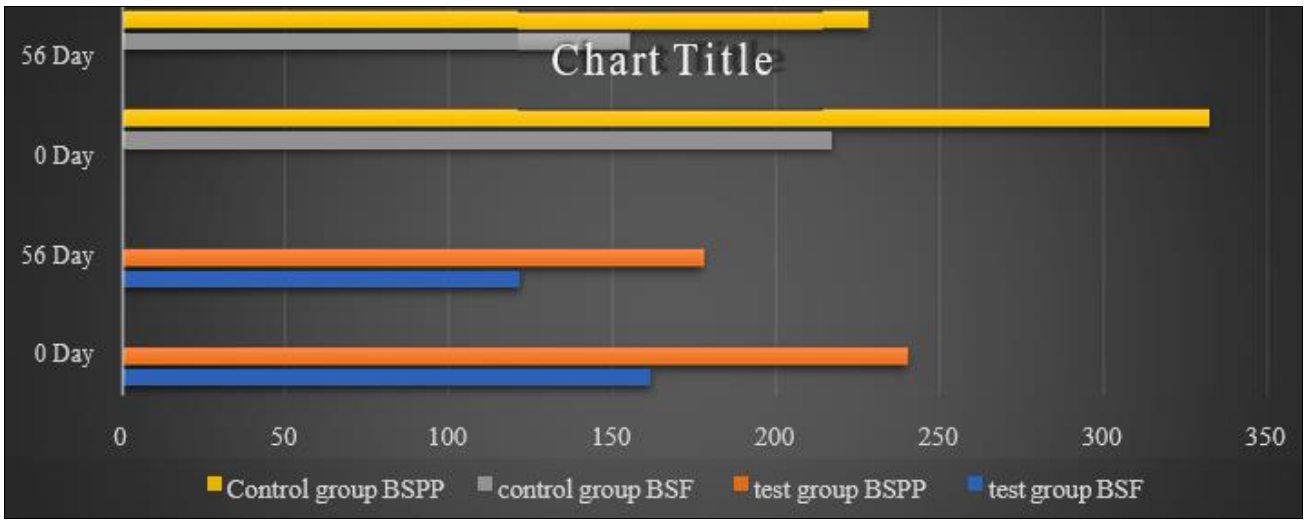

Fig 1: Intergroup Comparison of Test group vs Control group on blood sugar Fasting & Post Prandial

Effect of Medications on clinical features

In the test group there was an improvement of 41.47% in polyuria, 52.05% in polydipsia, 54.47% in polyphagia, 71.11% in tiredness, 48.54% in nocturia, 36% in numbness, 73.91% in cramps and 76.92% in burning of palms / soles at the end of the study.

While in control group there was improvement of 59.28% in polyuria, 46.23% in polydipsia, 43.52% in polyphagia, 61.52% in tiredness, 62.5% in nocturia, 14% in numbness, 23.07% in cramps and 0% in burning of palms / soles at the end of the study.

Table 3: Effect of trial drug on symptoms of Test group

F/U in Days	Before Treatment	After Treatment							
	0 days	14th day		28th day		42nd day		56th day	
Features	Total No. of patients	Number of patients	Improved %age	Number of patients	Improved %age	Number of patients	Improved % age	Number of patients	Improved % age
polyuria	30	30	11.36%	30	34.09%	30	41.47%	30	41.47%
polydipsia	30	30	17.80%	30	27.39%	27	36.30%	21	52.05%
Polyphagia	30	30	8.13%	28	31.95%	25	32.52%	17	54.47%
Tiredness	22	23	0%	22	11.11%	16	41.11%	8	71.11%
Nocturia	29	29	6.79%	27	12.62%	19	38.83%	16	48.54%
Numbness	7	7	0%	7	0%	7	0%	5	36%
Cramps	7	7	0%	5	30.43%	5	30.43%	2	73.91%
Burning of palms/soles	4	4	0%	4	0%	4	0%	1	76.92%

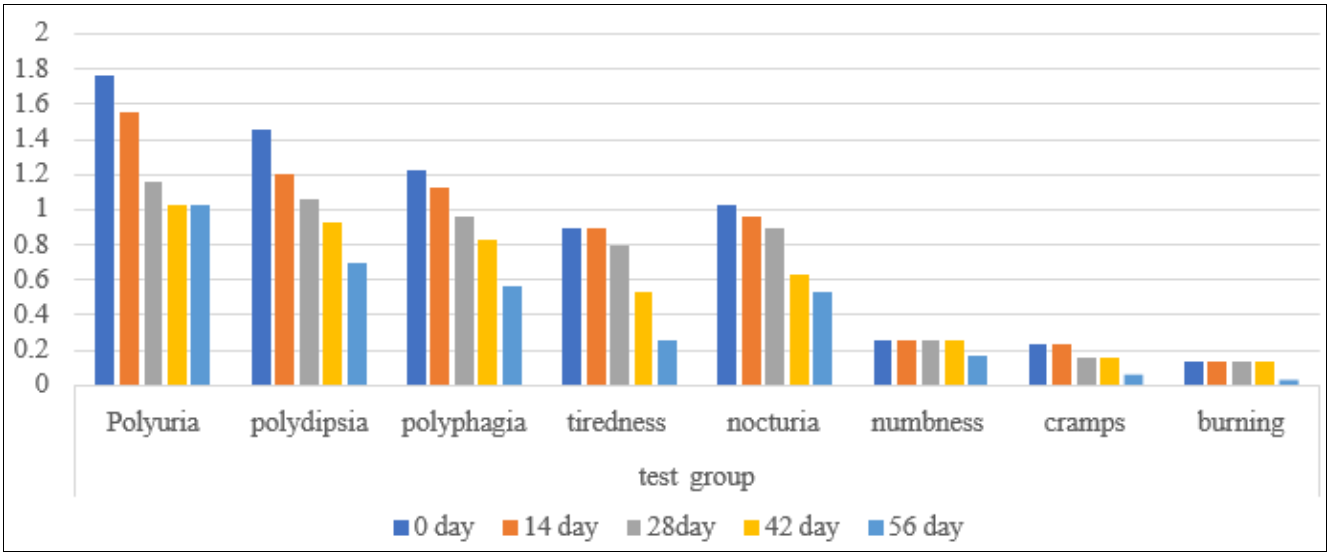

Fig 2: Effect of the Drug on symptoms of Test group

Table 4: Effect of the Drug on symptoms of Control group

F/U in Days	Before Treatment	After treatment							
	0 days	14th day		28th day		42nd day		56th day	
Features	Total No. of patients	Number of patients	Improved % age	Number of patients	Improved % age	Number of patients	Improved % age	Number of patients	Improved % age
polyuria	30	30	22.52%	30	39.52%	30	56.52%	30	59.28%
polydipsia	30	30	16.12%	30	43.01%	29	46.23%	29	46.23%
Polyphagia	30	30	27.64%	30	37.64%	29	41.17%	28	43.52%
Tiredness	30	30	17.34%	29	40.46%	28	42.19%	21	61.84%
Nocturia	30	30	27.5%	29	40%	28	41.87%	21	62.5%
Numbness	15	15	0%	15	0%	15	0%	13	14%
Cramps	8	6	23.07%	6	23.07%	6	23.07%	6	23.07%
Burning of palms/soles	9	9	0%	9	0%	9	0%	9	0%

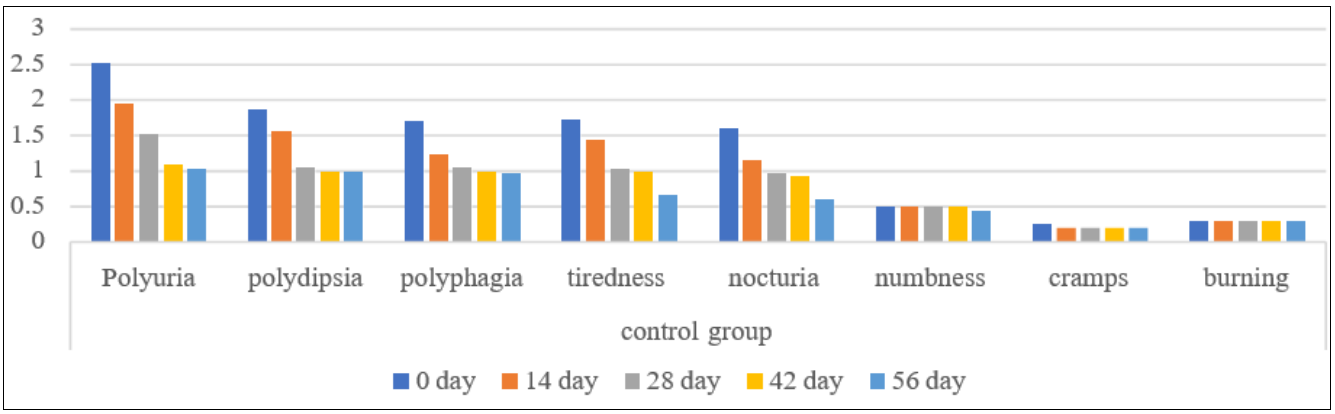

Fig 3: Effect of the Drug on symptoms of control group

Table 5: Intergroup comparison on subjective parameters (relieved)

Parameters	Test group	Control group
Polyphagia	54.47%	43.52%
Polyuria	41.47%	59.28%
Polydipsia	52.05%	46.23%
Nocturia	48.54%	62.5%
Numbness	36%	14%
Cramps	73.91%	23.07%
Tiredness	71.11%	61.52%
Burning of palm & soles	76.92%	0%

Effect of trial drugs on cholesterol in both groups

It was observed that in test group mean serum cholesterol level was 173.63 before the beginning of treatment which got reduced to 157.7 at the end. As we applied paired 't' test to the observation the effect of drug was found highly significant.

In control group the mean serum cholesterol level was 175.76 before the beginning of the treatment which got reduced to 165.06 at the end and the level was always within the normal range. As we applied paired 't' test to the observation the effect was found significant.

Table 6: Effect on cholesterol in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ± SD	175.76 ± 20.16	165.06 ± 16.48	173.63 ± 18.32	157.7± 12.73

Effects of trial drugs on triglycerides in both groups

In the test group the mean serum triglyceride level was 174.86 before starting the treatment, which got reduced to 155.16 at the end of the treatment. On applying paired 't' test after the treatment we found the drug highly significant.

In control group the mean serum triglyceride level was 175.3 which got decreased to 162.01 at the end of the treatment and the level was always within the normal range. On applying paired 't' test after the treatment we found the drug significant.

Table 7: Effects on Triglyceride in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ±SD	175.3 ± 62.8	162.01 ± 66.98	174.86 ± 56.14	155.16 ± 42.73

Effects of trial drugs on HDL in both groups

In the test group the mean serum HDL was 43.96 before beginning the treatment which got decreased to 43.90 at the end of the treatment and the level was always within the normal range, on applying paired 't' test, we found the effect of drug in increasing the HDL insignificant.

In control group the mean serum HDL was 43 before beginning of the treatment which got decreased to 42.5 at the end of the treatment and the level was always within the normal range. On applying paired 't' test, we found the effect of drug in increasing the HDL insignificant.

Table 8: Effects on HDL in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ± SD	43 ± 5.14	42.5 ± 4.51	43.96 ± 5.45	43.9 ± 6.68

Effects of trial drugs on LDL in both groups

In the test group the mean serum LDL was 95.06 before beginning the treatment which got reduced to 85.28 at the end of the treatment and the level was always within the normal range, on applying paired 't' test we found the effect of drug in reducing the LDL significant.

In control group the mean serum LDL was 97.85 before beginning of the treatment which got dropped to 94.68 at the end of the treatment and the level was always within the normal range. On applying paired 't' test we found effect of the drug in reducing the LDL insignificant.

Table 9: Effects on LDL in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ± SD	97.85 ± 15	94.68 ± 17.77	95.06 ± 18.56	85.28 ± 22.43

Safety Parameters

In this study safety parameters *viz*. Hemogram, Liver function test and Kidney function test were also assessed at baseline, 10th day and after the protocol therapy was over. On statistical analysis of the data no considerable difference was observed in both the groups. During the entire period of study, no adverse / side effects were reported.

Effects of trial drugs on SGOT in both groups

In test group the mean SGOT was 32 before the starting of the treatment which got increased to 34 at the end of the study and the level was always within the normal range. On applying paired 't' test it was found that the effect of the drug was insignificant.

While in control group the mean SGOT level was 27.23 before the starting of the treatment which got increased to 33.93 at the end of the treatment and the level was always within the normal range. On applying paired 't' test it was observed that the effect of the drug was insignificant.

Table 10: Effects on SGOT in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ± SD	27.23± 9.35	33.93 ± 8.85	32 ± 11.7	34 ± 8.44

Effects of trial drugs on SGPT in both groups

In test group the mean SGPT level was 38.6 at the beginning of the treatment which got increased to 40.46 at the end of the treatment and the level was always within the normal range. On applying paired 't' test it was found that the effect of the drug was insignificant.

While in control group the mean SGPT level was 28.13 at the beginning of the study which got increased to 35.06 at the end of the study and the level was always within the normal range. On applying paired 't' test we found that the effect of the drug was insignificant.

Table 11: Effects on SGPT in both groups

	Control group		Test group	
F/U visits	0 day	56th day	0 day	56th day
Mean ± SD	28.13 ± 9.9	35.03 ± 6.84	38.6 ± 18.44	40.46 ± 19.25

Effects of trial drugs on ALP (Alkaline Phosphatase) in both groups

In test group the mean ALP level was 142.06 at the beginning of the treatment which got increased to 147.53 at the end of the treatment and the level was always within the normal range. On applying paired 't' test it was found that

the effect of the drug was insignificant.

While in control group the mean ALP level was 145.7 at the beginning of the study which got increased to 148.56 at the end of the study and the level was always within the normal range. On applying paired 't' test we found that the effect of the drug was insignificant.

Table 12: Effects on ALP in both groups

	Control group		Test group	
F/U visits	**0 day**	**56th day**	**0 day**	**56th day**
Mean ± SD	145.7 ± 16.6	148.56 ± 13.89	142.06 ± 12.29	147.53 ± 19.13

Table 13: Safety assessment for Test group (n=30)

Parameters		Assessments		
		0 Day	**10th Day**	**56nd Day**
Haemoglobin		12.91	12.98	12.98
TLC		7803.33	7198.33	7736.66
DLC	Polymorphs	66.03	66.3	65.4
	Lymphocytes	30	30.9	31.63
	Eosinophils	3.83	2.93	2.93
	Basophils	0	0	0
	Monocytes	0	0	0
LFT	SGOT	32	34.2	34
	SGPT	38.6	39	40.46
	S. Alk. Phos.	142.06	144.2	147.53
KFT	B. Urea	28.93	31.8	31
	S. Creatinine	0.84	0.81	0.78

Table 14: Safety assessment for Control group (n=30)

Parameters		Assessments		
		0 Day	**10th Day**	**56nd Day**
Haemoglobin		12.75	12.58	12.72
TLC		7484.66	7170	6473.33
DLC	Polymorphs	64.46	66.03	66.96
	Lymphocytes	32.4	30.9	30.5
	Eosinophils	3.13	3	2.66
	Basophils	0	0	0
	Monocytes	0	0	0
LFT	SGOT	27.23	30.9	33.93
	SGPT	28.13	31.6	35.03
	S. Alk. Phos.	145.7	144.63	148.56
KFT	B. Urea	32.06	33.53	37.06
	S. Creatinine	0.8	0.81	0.79

Discussion

In this study 11(18.33%) patients and 5(8.33%) patients were smokers and tobacco chewers respectively. Many studies revealed that smokers are 30 to 40 percent more likely to develop type 2 diabetes than non-smokers. It can also make it difficult to manage the diabetes and regulate insulin levels [24].

In this study a positive family history of diabetes was found in 9(15%) patients. Family history have shown that there are high chances of developing diabetes, if the parents of a person are diabetic.

In the test group there was an improvement of 41.47% in polyuria, 52.05% in polydipsia, 54.47% in polyphagia, 48.54% in nocturia, 36% in numbness, 73.91% in cramps and 76.92% in burning of palms / soles.

In control group there was improvement of 59.28% in polyuria, 46.23% in polydipsia, 43.52% in polyphagia, 61.52% in tiredness, 62.5% in nocturia, 14% in numbness, 23.07% in cramps and 0% in burning of palms / soles.

The trial formulation is found better in controlling polydipsia, polyphagia, tiredness, numbness, cramps and burning palms and soles, whereas the control drug is found superior in controlling the symptoms of polyuria and nocturia.

In the present study, all patients pursued lifestyle modifications as suggested during the course of trial. They were advised to take diabetic diet of 1800 k/cal consisting of low fat and carbohydrate diet along with 45 min of physical activity at least 5 days in a week.

During the course of the study, with the improvement in clinical features, we took care of adverse effects of the drugs at subsequent visits. All of the patients showed good tolerability to the trial formulation. Every patient of test group has shown improvement in sign & symptoms of diabetes mellitus at the end of the study.

Laboratory profile suggests that during the trial lipid profile, blood sugar levels, kidney function test in the test group improved significantly. It indicates that Unani formulation not only decreased the blood sugar level significantly but also reduced the risk factors of Diabetes Mellitus Type 2. Besides this, no adverse / side effects were observed during the course of the study, rather the drug has been found absolutely safe and efficacious.

Conclusion

The results of this study can be concluded as follows:

There was statistically significant reduction in the blood sugar fasting and post prandial levels in the test group as well as control group patients.

The Unani formulation as well as the control drug improved the clinical features of the disease significantly. However, trial formulation is found better in controlling polydipsia, polyphagia, tiredness, numbness, cramps and burning palms and soles, whereas the control drug is found superior in controlling the symptoms of polyuria and nocturia.

The Unani test formulation was well tolerated and no adverse/side effects were observed during the entire period of protocol therapy.

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