

Efficacy of Spirulina (Tahlab) in Patients of Type 2 Diabetes Mellitus (Ziabetes Shakri) - A Randomized Controlled Trial

Anzar Alam^{1*}, Siddiqui MA², Aleemuddin Quamri², Sana Fatima³, Mariyam Roqaiya⁴ and Zaheer Ahmad⁵

¹Department of Moalajat, Luqman Unani Medical College Hospital and Research Centre, Bijapur, Karnataka, India

²Department of Moalajat, National Institute of Unani Medicine, Kottigepalya, Bengaluru, Karnataka, India

³Department of Pharmacy, National Institute of Unani Medicine, Kottigepalya, Bengaluru, Karnataka, India

⁴Department of Ilmul Qabala wa Amraze Niswan, Luqman Unani Medical College Hospital and Research Centre, Bijapur, Karnataka, India

⁵Research Officer (Unani) S-4, RRIUM, Chennai, India

Abstract

Aims: Diabetes mellitus (DM) (*Ziabetes Shakri*) is a common metabolic disease affecting 150,000,000 people worldwide. Despite the recent advancements in management of Diabetes its relative co-morbidities and mortality is ever increasing globally. Unani scholars had claimed the effectiveness of several anti-diabetic drugs in the classical texts in the management of DM, but it lacks scientific documentation. Hence, a clinical trial was contemplated to evaluate the efficacy of test drug *Tahlab* (*Spirulina*) in patients of type 2 DM.

Methods: The study was a single blind randomized standard control conducted on 40 patients of type 2 DM. 30 subjects were allocated to test and 10 to control group. Test group received 7 grams of *Tahlab* powder twice a day, and control group received Metformin (500 mg) 1 tablet twice a day for a period of 45 days. Subjective and objective parameters were assessed at 0, 15th, 30th, 45th day.

Results: The Mean score for FBS in test group has declined from 245.53 to 204.87 and PPBS from 345.73 to 303.67 respectively. The Mean score for FBS in control group has declined from 227.60 to 191.80 and PPBS from 329.60 to 282.80 respectively. Intergroup comparison revealed test drug to be similar to that of control drug in reducing FBS and PPBS. HbA1c and urine sugar remained unaltered in both groups. The results were assessed statistically using two tailed student t test, paired proportion test and Fischer exact test.

Conclusions: The study revealed that the test drug is safe and equally effective when compared to control drug.

Keywords: Type 2 Diabetes mellitus; Spirulina; Tahlab; Ziabetes

Highlights

- Tahlab (Spirulina) has been claimed by the ancient Unani physicians in the classical texts to be effective in the treatment of Diabetes like condition.
- Globally strenuous efforts are underway to explore herbal therapies to treat Diabetes mellitus which has become a menace for the Asian population as its prevalence is increasing at an alarming rate.
- Tahlab has been found to be equally effective when compared to control drug sans adverse effects.

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 described by renowned Unani scholars like Zakaria Razi, Ali Ibn Abbas Majoosi, Ibn Sina, Ismail Jurjani, Ibn Zuhar, Ibn Hubal Baghdadi, with various names such as; Ziabetes, Moattasha, Atsha, Intesae Anmas, Zalaqul kulliya, Dolab, Dawwarah, Barkar, Barkarya, Qaramees etc. [2-7]. 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 scholars, diabetes is considered as disease of kidney and it is due to four causative factors (i) zofe kuliya (weakness of kidney) (ii) Ittesae kuliya wa majrae bole (dilatation of kidney and tubule) (iii) sue mizaj haar kuliya (derangement of temperament of kidney due to heat) and (iv) sue mizaj barid kuliya (derangement of temperament of kidney due to cold) [2-7].

Unfortunately, until date there is no appropriate therapeutic intervention to treat the diabetes. Currently, biguanides, sulphonylureas, insulin and including DPP-4 Inhibitors are used to manage the diabetes

***Corresponding author:** Dr. Anzar Alam, Assistant Professor, Department of Moalajat, Luqman Unani Medical College, 12 Naubag, Bijapur, Karnataka, India, Tel: +91-9902146030; E-mail: dranzarnium@gmail.com

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[12]. Long terms usage of these drugs leads to various complications and adverse effects; renal problem, hypoglycemia, gastro intestinal tract (GIT) disturbance and cardiac problems [13]. The above fact necessitates the exploration of time tested, effective and safe Unani treatment for the management of diabetes.

Currently, Spirulina (a single cell filamentous algae, richest source of protein, nature best food) is documented as; antioxidant & immunomodulator [14], hepatoprotective [15], nutraceutical [16], nephroprotective [17] neuroprotective [18], cardioprotective [19], anticarcinogenic [20], anti dyslipidaemic and anti hyperglycaemic activity [21]. Another study reported that insulin like protein is found in Spirulina [22].

In Unani literature Spirulina is described by the name of tahlab which means green vegetation substance sticking to the walls of pond water and was used in the management of diabetes from ancient times and its action is ascribed to its baroodat wa yaboosat (cold and dry) temperamental property and astringent activity. Most of the antidiabetics Unani drugs are astringenic in action including tahlab [23,24].

A number of independent preclinical and clinical studies support the antihyperglycaemic and antidyslipidaemic activity for spirulina [21,25-32]. These observations led us to contemplate the study to evaluate the safety and efficacy of spirulina (tahlab) in the management of Type 2 Diabetes in human subjects.

Materials and Methods

A randomized single blind standard controlled trial was conducted during March 2014 to July 2014 at the O.P.D of N.I.U.M, Bengaluru. The study protocol was approved by the Institutional Ethical Committee of National Institute of Unani Medicine, Karnataka (IEC No: NIUM/IEC/2012-13/001/Moal/01). The test drug Spirulina was procured from Avantha Holdings Limited Spirulina Biotech Division, K.I.A.D.B. Industrial Area, Nanjangud Karnataka-571302, in the form of powder. Each patient in test group was given spirulina in a dose of 7 g twice

a day in powder form and the control drug Glycomet (Metformin) (Manufactured by USV Company) in a dose of 500 mg, one tablet was given orally twice a day before meal for 45 days.

Selection criteria include diagnosed cases of type 2 DM with Fasting Blood Sugar (FBS)>126 mg/dl, Post Prandial Blood Sugar (PPBS)>200 mg/dl, HbA1c>6.5% and aged between 30-60 years of either gender, patients willing to participate in the study and ready to follow the instructions. Exclusion criteria include pregnant and lactating women malnutrition related diabetes mellitus, diabetic ketoacidosis, retinopathy, neuropathy, nephropathy, coronary artery diseases, peripheral vascular disease, cerebrovascular disease, liver disease and impaired organ functions (Figure 1).

A total no of 40 subjects of diabetes fulfilling the inclusion criteria were randomly assigned to the test and standard controlled group by simple randomization method after taking voluntary informed consent. Thirty subjects were allocated to test group and 10 subjects to the standard control group. Subjective parameters (polyuria, polydipsia, polyphagia and tiredness) were assessed at baseline and follow up visits (15th, 30th and 45th days) and assessment of objective parameters (fasting blood sugar, post prandial blood sugar, HbA1c and urine sugar) were carried out on pre and post (i.e. 0th and 45th days) study period.

Descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented as Mean \pm SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Student t test (two tailed, independent) was used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters and Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Paired Proportion test has been used to find the significance of proportion in paired data using standard statistical software. The Statistical software SAS 9.2, SPSS 15.0,

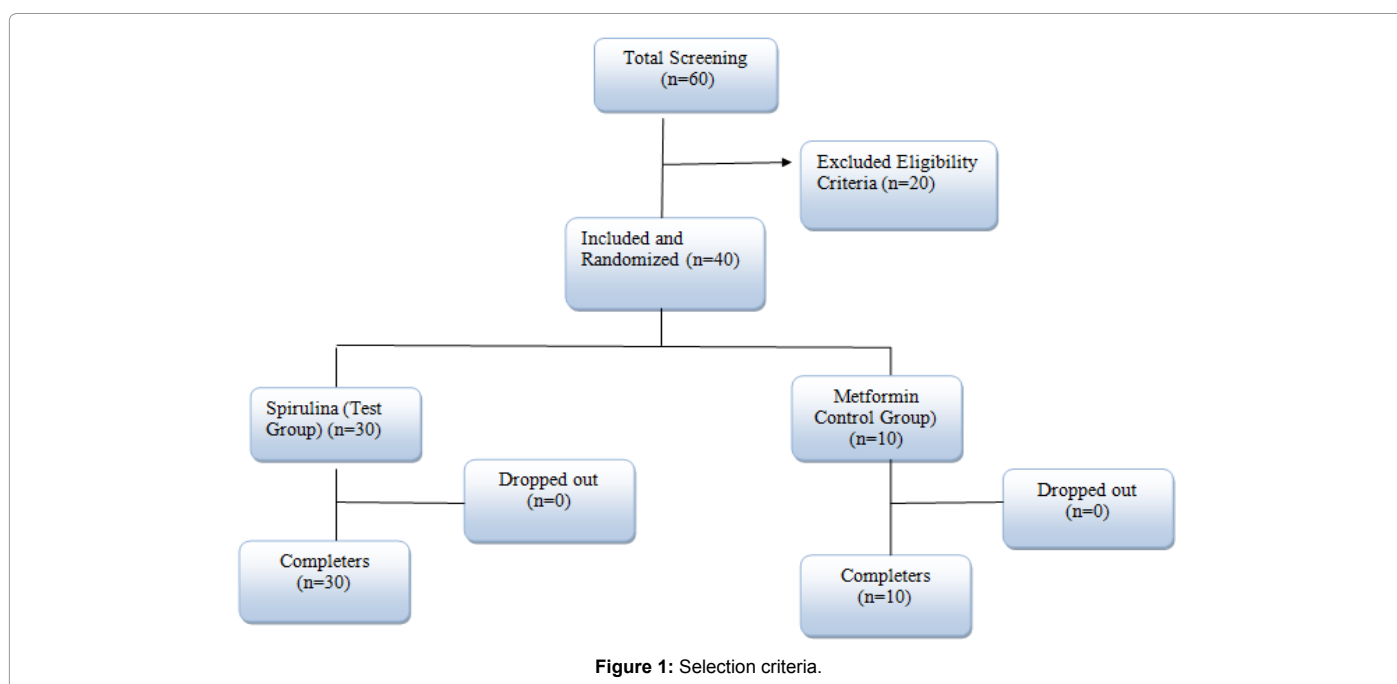


Figure 1: Selection criteria.

Stata 10.1, Med Calc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data.

Results and Discussion

As depicted in Table 1 that maximum number of patients 28 (70%) were recruited in age group of 41-60 years and only 12 (30%) were <40 years. According to IDF Diabetes Atlas 6th Edition, 382 million people with diabetes are aged between 40 and 59 years [11]. This study coincides with the IDF finding as more numbers of subjects were between 41-50 years followed by 51-60 years. Highest incidence 30 (75%) was observed in male patients while 10 (25%) are female patients. This study finding support the claim made by Khalid et al. that prevalence of diabetes is more among males than in females [33]. Out of 40 patients, 32(80%) were found to be normal without any concomitant diseases, whereas, 7 (17.5%) were hypertensive and 1 (2.5%) had complicated diabetes mellitus (Table 1). Samuels et al. made almost similar observations [34]. The duration of illness was between 24-60 months in 9 (22.5%) patients, 12-24 months in 14 (35%) patients, 7-12 months in 4 (10%), 4-6 months in 3 (7.5%), 1-3 months in 5 (12.5%), and >60 months in 5(12.5%) (Table 1). Verma et al. reported that tendency of diabetes increases with increasing duration of illness, which is not consistent with the study due to low sample size [35]. Dietary habit was mixed in 39 (97.5%) patients and only 1(2.5%) patient was pure vegetarian (Table 1). Tonstad et al. reported that DM more is common in non-vegetarians than vegetarians and vegetarians had low risk of type-2 diabetes than non-vegetarians [36]. Among 40 patients, 24 (60%) had positive family history of DM (Table 1). Shah et al. reported that family history of diabetes is the predisposing factor for type-2 DM [10].

Effect on subjective parameters

Test and control groups were assessed for polyuria on the arbitrary rating scale of nil, mild, moderate and severe polyuria. It was found that test group showed 56.6% reduction in polyuria compared to 80% reduction in control group. In both the groups, the reduction in polyuria was significant statistically ($P<0.001$). Reduction of polyuria in test group may be due to Qabiz (astringent) property of Spirulina (Tahlab) [37]. In polydipsia, 60% improvement in test group compared to 0% in Nil and 10% in mild category, which is statistically significant ($P<0.001$) at 45th day compared to control group ($P=0.069+$). The effect may be due to Musakkin Atash, Qabiz and Mubarrid property of the drug described by Zakaria Rhazi, Ibn Baitar, Hkm. Kabiruddin [37-39]. Polyphagia has significantly improved ($P<0.001$) to 40% in test group compared to 10% in controls which may be due to highly nutritious and energetic effect of spirulina reported by Ravi et al. [14]. Tiredness is improved in 40% cases in test group compared to 20% in control group. Park et al. [39] reported that Spirulina contains various vitamins and minerals, which act as immunomodulators and antioxidant properties, which prevent the formation of lactic acid and reduced the tiredness [40].

Objective parameters

The Mean \pm SEM score for FBS in Test Group on 0th day and 45th day was 245.53 \pm 78.95 and 204.87 \pm 78.15 respectively, with a difference of 40.667. The Mean \pm SEM score 227.60 \pm 67.85 and 191.80 \pm 78.91 on 0th day and 45th day respectively, with a difference of 35.800 in Control Group which is statistically significant (Table 2). Parikh et al. affirmed that spirulina is rich source of fibre contents which may leads to reduced glucose absorption and possible action of peptides and polypeptides generated by digestion of spirulina protein are responsible for it [21]. Kumari et al. [26], Anitha et al. [30], Lee et al. [31], Kaur et

al. [32], and Layam et al. [41], reported that Spirulina exhibit anti-hyperglycemic activity.

The Mean \pm SEM score for PPBS in Test Group was 345.73 \pm 98.33 and 303.67 \pm 96 on 0th day and 45th day respectively, with a difference 42.067. The mean \pm SEM score in control group has declined from 329.60 \pm 72.92 to 282.80 \pm 99.90 on 0th day and 45th day respectively, with a difference of 46.800, which is statistically moderately significant (Table 2). Parikh et al. and Anwer et al., reported that Spirulina provides plentiful source of proteins and it is well recognized that ingestion of protein and amino acids which stimulates the secretion of insulin. This effect may be responsible for reduction in PPBS [21,22].

The Mean \pm SEM score for HbA1c in Test Group as observed on 0th day and 45th day was 9.73 \pm 1.92 to 9.95 \pm 2.11 respectively, with a difference of 0.220. The Mean \pm SEM score observed in control group was 9.61 \pm 1.49 to 9.15 \pm 2.03 on 0th day and 45th day respectively, with a difference of 0.460 in Control Group (Tables 3 and 4). When Mean

	Test Group	Control Group	Total
Age in years			
<30	1 (3.3%)	0 (0%)	1 (2.5%)
31-40	7 (23.3%)	4 (40%)	11 (27.5%)
41-50	16 (53.3%)	4(40%)	20(50%)
51-60	6 (20%)	2 (20%)	8 (20%)
Total	30 (100%)	10 (100%)	40 (100%)
Mean \pm SD	45.07 \pm 7.67	44.00 \pm 9.39	44.80 \pm 8.02
Family history			
DM	18 (60%)	6 (60%)	24 (60%)
NS	12 (40%)	4 (40%)	16 (40%)
Total	30 (100%)	10 (100%)	40 (100%)
Past history			
NS	23 (76.7%)	9 (90%)	32 (80%)
HTN	7 (23.3%)	0 (0%)	7 (17.5%)
DM	0 (0%)	1 (10%)	1 (2.5%)
Duration of Illness			
1-3 months	4 (13.3%)	1 (10%)	5 (12.5%)
4-6 months	2 (6.7%)	1 (10%)	3 (7.5%)
7-12 months	3 (10%)	1 (10%)	4 (10%)
12-24 months	9 (30%)	5 (50%)	14 (35%)
24-60 months	8 (26.7%)	1 (10%)	9 (22.5%)
>60 months	4 (13.3%)	1 (10%)	5 (12.5%)
Total	30 (100%)	10 (100%)	40 (100%)
Dietary habits			
Mixed	29 (96.7%)	10 (100%)	39 (97.5%)
Veg.	1 (3.3%)	0 (0%)	1 (2.5%)
Total	30 (100%)	10 (100%)	40 (100%)

Table 1: Demographic profile of the patients in the study groups.

FBS	Test Group	Control Group	Total	P value
0th day	245.53 \pm 78.95	227.60 \pm 67.85	241.05 \pm 75.89	0.525
45th day	204.87 \pm 78.15	191.80 \pm 78.91	201.60 \pm 77.53	0.65
Difference	40.667	35.8	39.45	-
P value	0.003**	0.212	0.001**	-
PPBS				
0th day	345.73 \pm 98.33	329.60 \pm 72.92	341.70 \pm 92.01	0.637
45th day	303.67 \pm 96.16	282.80 \pm 99.90	298.45 \pm 96.24	0.56
Difference	42.067	46.8	43.25	-

Table 2: FBS (mg/dl) in two groups of patients studied.

HbA1c	Test Group	Control Group	Total	P value
0th day	9.73 ± 1.92	9.61 ± 1.49	9.70 ± 1.80	0.862
45th day	9.95 ± 2.11	9.15 ± 2.03	9.75 ± 2.09	0.303
Difference	0.22	0.46	0.05	-
P value	0.525	0.459	0.867	-

Table 3: HbA1c in two groups of patients studied.

Urine Sugar	0 d	45 d	% change
Test Group (n=30)			
Nil	7 (23.3%)	8 (26.7%)	3.40%
Trace	0 (0%)	3 (10%)	10.00%
0.5	2 (6.7%)	2 (6.7%)	0.00%
1	5 (16.7%)	4 (13.3%)	-3.40%
1.5	2 (6.7%)	1 (3.3%)	-3.40%
2	13 (43.3%)	12 (40%)	-3.30%
2.1	1 (3.3%)	0 (0%)	-3.30%
Control Group (n=10)			
Nil	1 (10%)	4 (40%)	30.00%
Trace	0 (0%)	1 (10%)	10.00%
0.5	2 (20%)	0 (0%)	-20.00%
1	2 (20%)	1 (10%)	-10.00%
1.5	2 (20%)	1 (10%)	-10.00%
2	3 (30%)	3 (30%)	0.00%
2.1	0 (0%)	0 (0%)	0.00%
P value	0.518	0.926	-

Table 4: Urine Sugar in two groups of patients studied.

± SEM score of HbA1c in both groups were compared statistically by using Student t test (two tailed, independent) it was found to be insignificant.

No change in the sugar in urine was observed in both the groups when compared statistically. The safety and tolerability of both test and control drugs were assessed at pre and post treatment i.e. Hb%, TLC and DLC, Blood Urea, Serum Creatinine, SGOT, SGPT, Urine Routine, Urine Microscopic, and ECG. The study revealed that all the safety parameters were within the normal range, and did not exhibit any significant difference demonstrating the tolerability of the test and control drugs.

The limitations of the study are small sample size, shorter duration of therapy, non-performance of serum insulin test etc. Hence, this trial open up new vistas in the exploration of herbal origin drugs in the management of DM and may serve as basal information to conduct more stringent studies in future.

Conclusion

The study has further enhanced and revealed the hypoglycemic nature of the test drug Spirulina. The reduction of subjective and objective parameters like polyuria, polydipsia, polyphagia, tiredness and FBS and PPBS demonstrate the utility of the intervention. Safety parameters remained within the normal range in both the groups throughout the course of trial suggesting that there is no Hepato/nephro toxicity. The study revealed the potential hypoglycemic activity of the test drug. However, a long-term study with a larger sample size is imperative to further validate its pharmacological actions.

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Conflict of Interest

Authors declare that there is no any conflict of interest involved in this study.

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