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Efficacy of *Kanduri* in type 2 DM (*Ziabetes Shakri*): A randomized single blind standard controlled clinical trial

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Abstract

Background and objectives: Diabetes is one of the largest global health emergencies of the 21st century. In Unani system of medicine Diabetes has been treating with several potent anti-hyperglycemic single drugs. To evaluate the effect of *Kanduri* (*Coccinia indica*) among patients of Diabetes Mellitus type II this study is conducted.

Methods: A single blind, randomized, standard control clinical trial on patients of Diabetes Mellitus Type II was conducted by randomly allocating the patients into two groups viz test (n=20) and control group (n=20) for a period of 8 weeks. Experimental group received 7.5 gram powder of dried leaves of *Kanduri* and control group received Tablet Metformin SR 500 mg. Both groups received drugs twice a day orally before meals. The study outcome was assessed with the difference in the objective findings of pre and post treatment.

Results: objective parameters like FBS, PPBS, HbA1c were found insignificant with $p > 0.05$.

Interpretation & Conclusion: This comparative trial revealed that interventions of both groups are effective in ameliorating the symptoms of *Ziabetes Shakri* in without any adverse effects.

Keywords: *Ziabetes Shakri*, *Kanduri*, *Coccinia indica*, DM Type 2

Introduction

Diabetes is a group of metabolic diseases characterized by hyperglycemia, which results from defects in insulin secretion, insulin activity or both. It is associated with the dysfunction and failure of different organs, such as the blood vessels, heart and kidneys^[1-7].

Several distinct types of DM are caused by a complex interaction of genetics and environmental factors. Depending on the etiology of DM, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization and increased glucose production^[8]. Type 2 DM has a high rate of genetic penetrance and is associated with obesity and a lack of physical activity^[9]. It accounts for the majority of DM encountered in clinical practice^[8]. Most of the times the diagnosis can be made only after the development of vascular or neuropathic complications.^[9] Worldwide, people are less physically active and this has become a leading risk factor for ill health as millions of lives are lost per year due to physical inactivity which leads to a host of disorders and DM is one of the four major NCDs (Cancer, Diabetes, Chronic respiratory and Cardiovascular diseases)^[10, 11] which account for most of the disease burden and premature mortality in the European Region. The WHO has projected that diabetes will be the 7th cause of death by 2030^[12, 13]. Further, the WHO estimates that globally, high blood glucose is the third highest risk factor for premature mortality, after high blood pressure and tobacco use^[14].

The latest scenario is that around 415 million people worldwide or 8.8% of adults aged 20-79 years are estimated to have DM. About 75% of diabetics live in low- and middle income countries. If the same trend continues then by 2040 about 642 million people i.e. one adult in every ten will have DM^[15]. The largest increase will take place in the regions where economies are moving from low-income to middle-income levels^[16]. According to a survey conducted in 2009 in India, more than 70 million individuals were diagnosed with the disease^[17] but at present the number of diabetics according to IDF 2015 is 69.2 million.

DM has a substantial economic impact on countries and national health systems [16]. Most of the countries spend between 5% and 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 complications, such as kidney failure, blindness or cardiac problems. With such a high cost, the disease is a significant challenge for healthcare systems and an obstacle to sustainable economic development [16-18].

In Unani literature *Al-Qanoon fit Tib, Al Hawi, Moalajat-e-Buqratiya, Kamil us San'a, Zakheera Khwarzam Shahi, Al-Mukhtarat Fit Tibb* [19] and a host of others there are adequate indications about the efficient use of many single drugs for DM since the Greco-Arab period. As an alternative approach single as well as compound formulations are sought after by the patients. Hence the need for alternative therapies for DM has increased globally because the patients worldwide have become aware of the fact that oral anti-hyperglycemics produce unfavourable effects in the long run. The first line treatment adopted in modern medicine is the use of Biguanides and Sulfonylurea for reducing hyperglycemia [8]. Many of the drugs mentioned in Unani literature have enough evidence regarding their effective use in DM since long but they need clinical assessment in the vision of scientific approach.

The drugs, to name a few, which would provide *tabreed* and *tarteeb* are *Kahu, Khashkhash, Kafoor, Neelofer, Aab-e-Kaddu, Aab-e-Khayaar, Aab-e-anaar tursh, Aab-e-toot, Aqaqiya and Samghe-e-arbi* etc. [20]

Clinical evaluation in the light of modern parameters is one of the areas which is selected for research in Unani system of Medicine. In recent years extensive researches have been carried out to explore the efficacy of Unani drugs and it has been revealed that many of them possess potent anti-hyperglycemic properties out of such anti-hyperglycemic herbs a single herb *Kanduri (Coccinia indica)* also believed to possess anti-dyslipidemic properties has been chosen for study [21]. So it is hypothesized to compare the effects of *Kanduri* leaves [22, 23] with that of a standard drug Metformin having similar properties [24].

Material Methods

This study was conducted to evaluation of the effect of *Kanduri (Coccinia indica)* in patients of Diabetes mellitus type II, as a randomized single blind standard controlled, and carried out at the Department of Moalajat, National Institute of Unani Medicine (NIUM), Bengaluru between March 2015 to February 2016 after the approval of the Institutional Ethical Committee for Biomedical Research of NIUM vide No (NIUM/IEC/2013-14/006/Moal/06) dated 24-04-2014.

The eligible patients enrolled into the study based on the inclusion criterion, after taking written informed consent, a total of 40 subjects were randomly allocated into Experimental group (n= 20) and control group (n= 20) with the help of computer generated randomization table, and the study was conducted for the duration of 56 days

Criteria for Selection of Subjects

Inclusion criteria: Known cases of DM with < 3yrs of disease history, with or without mono drug therapy, Fasting blood Glucose \geq 126 mg/dl - < 200mg/dl, Post Prandial Blood Glucose \geq 140 mg/dl - < 300mg/dl, HbA_{1c} > 6.5% -

< 10%, Patients between 35-60 years of age, Both gender, Normotensives (< 130/ 80 mm of Hg).

Exclusion Criteria: Post Prandial blood Glucose < 140 mg/dl \geq 300mg/dl, HbA_{1c} < 6.5% - \geq 10%, Pregnant & lactating mothers, History of any systemic illnesses, and hypertension >130 – 80 mm of Hg, History of any other disorders of metabolism with

Objective parameters: Blood Glucose-Fasting and Post Prandial and HbA_{1c}.

Data analysis

Analytical tests were carried out using InStat Graph Pad. These tests were paired t test, Wilcoxon matched pair test and Friedman test for intra group comparison and one way ANOVA and Kruskal- Wallis test with Dunn's multiple pair comparison for inter group comparison.

Result

A total of 200 patients were screened between March 2015 to February 2016, out of which 40 eligible patients gender wise 19 males and 21 females with a mean age of 44.05 ± 8.118 years were enrolled into the study after obtaining written informed consent and randomly allocated with the help of computer generated randomization table into two groups of 20 each. Experimental group was receiving 7.5 grams powder of dried leaves of *Kanduri* and control group received Tablet Metformin SR 500 mg twice a day before meal orally for 8 weeks.

The demographic characteristics of the two study groups are shown in Table -1. There were no significant differences between the groups at baseline. The subjective and objective parameters of baseline observation and at the end of 8th week with the mean differences are shown in Table- 2 to 10. Objective parameters like FBS, PPBS, HbA_{1c} were found insignificant with $p > 0.05$.

Discussion

Out of 36 patients who completed the study, a maximum of 18 (50%) patients were found in the age group of 35-40 years, [26] followed by 14 (39%) in 46-55 years and 4 (11%) in 56-60 years. This data indicates type 2 DM is seen in individuals in their 3rd or 4th decades of life. This finding supports the observations made by IDF 2015 [16] in which it is mentioned that DM is a disease of middle aged and elderly also reported by Suastika *et al.* [27] In this study 21 patients (58%) were found to be females and 15 (42%) were males. This finding supports the prevalence of the disease as higher in females than males according to observations made by Kaur *et al.* [28] where the premenopausal aged females are more prone to develop the disease on the contrary Qutubuddin [29] and IDF [16] reports that this disease is more prevalent in males than females. This study reveals that 32 (89%) patients were married, 2 (5.5%) unmarried and 2 (5.5%) widows. As such no specific relationship is established with the disease and marital status, Shamsalinea *et al.* [30] reveals that positivity in married life has no influence on chronic diseases as such and diabetes is one among them. This study evidences that 31 (86%) patients were having mixed dietary habit and 05 (14%) were pure vegetarian. Diet has a very significant causal relationship with this disease. Many clinical study based data are available to suggest the relationship of diet with disease as

observed by Rizwana *et al* [31] and Jitendra *et al*. [32] The main focus of IDF, on the occasion of World Diabetes Day in 2015, on diet and exercise is an indicator in itself as to how important diet is in the management of the disease. "Jitendra *et al* [32] claims that the disease can be prevented by an active lifestyle and it is seen that out of 36 subjects 14 (38.88%) had a sedentary life style, followed by 13 (36.11%) mild activities, 8 (22.2%) moderate activities and only 1(2.77%) patient was a hard worker and this is in conformity with Das *et al* [33] were it is proved that sedentary life plays an important role in the causation of the disease as is seen in this study.(Mild, moderate and hard work were catagorized according to the American Industrial Hygiene Association. Ramsey *et al*. [25] In this study the highest number of patients ie 20 (55.55%) were found with BMI of 25-30 followed by 10 (27.77%) with 19-24 and 6 (16.66%) 31-40.This indicates that prevalence of diabetes is high in the BMI range of 25-30 which is termed overweight and this is a major contributing factor for causing Diabetes. This finding coincides with the description of risk of diabetes by Mary G *et al* [34] were the risk of diabetes increases seven fold in obese individuals and three folds in overweight. From the present findings we can come to the conclusion that obesity accelerates the onset of diabetes and is a predisposing factor to the disorder.

Assessment of the Effects of Interventions on Objective Parameters

FBS: The effect of the study on "FBS" was derived from the mean scores with differences from base line to 1st, 2nd, 3rd, 4th follow ups in Experimental group observed as 148.2±27.6, 154.1±56.8, 159.2±52.0,156.2±48.3 and 156.2±53.3, whereas in control group it was 154.9±30.8, 152±40.7, 155.6±68.6, 154.5±51.3,156.2±42 (Table No.23). The mean scores of both groups were compared statistically using Repeated measure ANOVA for intra group and Mann Whitney U Test test for inter group comparison. The effect

of study in Experimental group and control group was observed to be non-significant. In intra group comparison p= 0.78 and in control group p= 0.99. Inter group comparison is statistically not significant and p value at "0" day is 0.861 and 4th follow up is 0.99. The effect was found to be statistically insignificant in both groups. A number of pre-clinical studies have claimed the hypoglycaemic effects of *Coccinia indica* and the same has been observed by Ramakrishnan *et al* [23] but such effects were not observed in our study and the influencing factors might be many.

PPBS: The effect of the study on "PPBS" was derived from the mean scores with differences from base line to 1st, 2nd, 3rd, 4th follow ups in Experimental group observed as 224.5±49.7, 242.3±81.5, 249.7±76.2, 251.9±65.9, 258.72±74.5 and in the control group it is as follows 268.4±62.3, 241.5±57.5, 244.8±90.9, 240.8±54.1, 252.3±46.3.(Table 24) The mean values of both groups were compared statistically using Repeated measure ANOVA for intra group and Mann Whitney U Test test for inter group comparison. The effect of study in Experimental group and control group was observed to be non-significant. In intra group comparison p= 0.13 and in control group p= 0.35. Inter group comparison is statistically not significant and p value at "0" day is 0.25 and 4th follow up is 0.75.

HbA1c: The effect of the study on "HbA1c" was derived from the mean values with differences from baseline to post test (56th day). Paired 't'test was used for intra group comparison and unpaired 't'test for inter group comparison. P value in intra group comparison for test and control is 0.33 and 0.95 respectively. Inter group comparison it is p=0.33 (Table no 25) This is in contrast to the findings of Bosenberg L H and Zyl van D G [35] where the property of Metformin is to bring a drop in HbA1C levels of 1 - 2% and similarly *Coccinia indica* is also known to have the properties which bring down the HbA1c level significantly.

Table 1: Demographic Data

S No	Demographic	Experimental Group		Control Group		
1	Age(Mean ±SD)	43.2±7.845		44.9 ±8.497		
2	Gender- Male /Female	10/12		9/9		
3	Marital Status- Married/Unmarried	17/1		17/1		
4	Dietary habits-Veg/Mixed	3/15		2/16		
5	BMI	19-24	7	39	3	17
		25-30	11	61	9	50
		31-40	0	0	6	33
		(Mean ±SD)	26.347±5.56		27.97±3.0	

Objective Parameters

Table 2: Effects of study on FBS among the groups in

FBS	BL	F1	F2	F3	F4	P value
Experimental Group	148.2±27.68	154.11±56.82	159.27±52.0	156.27±48.34	156.22±53.33	0.781
Control Group	154.94±30.84	152.05±40.78	155.66±68.65	154.5±51.33	156.22±42	0.994
P value	0.861				0.99	

Repeated measure ANOVA is used for intra group comparison with p value 0.7810 of Experimental group and 0.9942 of control group. Between groups, Mann Whitney U test for baseline and Unpaired T test for fourth follow up with p values 0.861 and 0.99 respectively.

Table 3: Effects of study on PPBS among the groups in

PPBS	BL	F1	F2	F3	F4	P value
Experimental Group	224.5±49.72	242.33±81.57	249.77±76.27	251.94±65.94	258.72±74.57	0.1342
Control Group	268.44±62.324	241.55±57.56	244.88±90.92	240.83±54.15	252.3±46.36	0.3541
P value	0.256				0.75	

Repeated measure ANOVA is used for intra group comparison with p value 0.1342 of experimental group and 0.3541 of control group. Between groups, Mann Whitney U test for baseline and Unpaired T test for fourth follow up with p values 0.256 and 0.75 respectively.

Table 4: Effect of HbA1c on groups in

Group	Assessment of HbA1c		
	Pre	Post	p value
Experimental group	7.783±1.206	8.077±1.414	0.338
Control group	8.233±1.513	8.75±1.22	0.954
P Value	0.3307	0.6983	

Conclusion

Diabetes is one of the challenging medical conditions globally; the existing chemical molecules though modulating the glycemic index but the effects are not sustained. Several herbs claims to be having anti hyperglycemic effect, one out of such Kanduri (*Coccinia indica*) is compared with Metformin. The study outcome validates the effect of Kanduri as oral hypoglycemic without any adverse effect, but found to be non-superior to metformin.

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Competing interests: None

References

- Olokoba AB, Olusegun AO, Olokoba LB. Type 2 Diabetes Mellitus: A Review of Current Trends Oman Med J. 2012; 27(4):269-273.PMCID: PMC3464757.
- Mohan V, Gundu HR Rao. Type 2 Diabetes in South Asians: Epidemiology, Risk Factors and Prevention. 1st ed. New Delhi: Jaypee Brothers Medical Publishers, 2007, 8-9.
- Genoveva Berná, María Jesús Oliveras-López, Enrique Jurado-Ruíz, Juan Tejado, Francisco Bedoya *et al.* Nutrigenetics and Nutrigenomics Insights into Diabetes Etiopathogenesis. 2014; 6(11):5338-69.
- Kallikazaros IE. Diabetes Mellitus: A Sweet-And-Sour Disease. Hellenic J Cardiol. 2013; 54:153-154.
- Anzar MA, Nafis H, Tanwir MA. Drugs Indicated For The Management of Ziaetus Shakri (Diabetes Mellitus) In Unani Medicine –An Overview. Int J Pharmamedix India. 2013; 1:460-474.
- Ahmed AM. History of Diabetes Mellitus. Saudi Med J. 2000; 23(4):373-378.
- Zajac J, Shrestha A, Patel P, Poretzky L. The Main Events in the History of Diabetes Mellitus. Principles of Diabetes Mellitus, 2010. DOI 10.1007/978-0-387-09841-8-1.
- Munjaj AP. Diabetes Mellitus. API Textbook of Medicine. Ninth edition. 2012, 321-393.
- Grover JK, Yadav S, Vats V. Medicinal plants of India with anti-diabetic potential. Journal of Ethnopharmacology. 2002; 81(1):81-100.
- Khan MA, Akseer-E-Azam. Urdu Translation by Hkm. Kabeeruddin. Idara Kitab Us Shifa New Delhi. 2011; 22:705-709.
- IDF UN High Level Summit on NCD's Sept, 2011.
- Anonymous. Definition and Diagnosis of DM and Intermediate Hyperglycemia. WHO/IDF, 2006.
- Kaveeshwar SA, Cornwall J. The current state of diabetes mellitus in India. The Australasian Medical Journal. 2014; 7(1):45-48.
- Akter S, Rahman MM, Abe SK, Sultana P. Bulletin of WHO 2014; 92:204-213A.
- Anonymous. WHO FACT SHEET JAN 2015.
- Anonymous. International Diabetes Federation. Six editions. 2013, 1-16
- Anonymous. Classification and Diagnosis of Diabetes. Diabetes Care. 2016; 39(1):S13-S22.
- Mithal A, Majhi A, Shanmugavelu M, Talverker PG, Vasnavela H. Prevalance of dyslipidemia in adult Indian diabetic patients. A cross sectional study (SOLID). Indian J of Endocrinol Metab. 2014; 18(5):642-47.
- Fazil M, Nikhat S, Akram M. Diabetes from Ancient to Modern Era. ISHIM. 2013; 14:164-68.
- Sina I, Al-Qanoon Fit-Tib. (Urdu translation by Kanturi G.H). New Delhi: Idara Kitab-al-Shifa. 3(2):1031-1033.
- Pekamwar SS, Kalyankar T, Kokate SS. Pharmacological Activities of Coccinia Grandis: Review Journal of applied pharmaceutical sciences may. 2013; (05):114-119.
- Kishore L, Kaur N, Chauhan S, Singh R. Phyto-Pharmacological Review of C Indica. WJPPS. 2014; 3(2):1734-23.
- Ramakrishnan M, Bhuvaneshwari R, Duraipandyan V, Dhandapani R. Hypoglycaemic activity of C. Indica in Alloxan-induced Diabetic rats. Indian Journal of Natural Products and Resources. 2011; 2(3):350-353.
- Aziz KMA. Unique Glycemic and Cardiorenal protective effects of Metformin therapy among Type 2 Diabetic patients with association of high non HDL Cholesterol and low HbA1c, Serum Creatinine and spot urine protein. Sci Med Central. Journal of Endocrinology, Diabetes & Obesity. 2014; 2(2):1033.
- Dinardi SR. The Occupational Environment: Its Evaluation, Control & Management. http://pos.brightdoc.com/store/preview_files/frontpgs_0pt.pdf. cited on 26/09/2017.
- Ozougwu JC, Obima KC, Belonwu CD. The Pathogenesis and Pathophysiology of Type 1 and Type 2 Diabetes. Academic Journals. 2013; 4(4):46-57.
- Katsuda Y, Kemmochi Y, Maki M. Effects of Unilateral Nephrectomy on Renal Function in Male Spontaneously Diabetic Torii Fatty Rats: A Novel Obese Type 2 Diabetic Model. Journal of Diabetes Research. 2014; 2014:363126.

25. Kaur T, Bishnoi D, Badaruddoza. Effect of sex on prevalence of type 2 diabetes mellitus (T2DM) with respect to blood pressure, BMI and WHR among Punjabi population. *International Journal of Medicine and Medical Sciences*. 2010; 2(9):263-270.
26. Shamsalinia A, Pourghaznein T, Parsa M. Relationship between Hope and Religious Coping among Patients with Type 2 Diabetes. *Global Journal of Health Science*. 2016; 8(1):208-216.
27. Mozafari M, Nekoeian AA, Panjeshahin MR, Zare HR. The Effects of Resveratrol in Rats with Simultaneous Type 2 Diabetes and Renal Hypertension: a Study of Antihypertensive Mechanisms. *Iranian Journal of Medical Sciences*. 2015; 40(2):152-160.
28. Kaur T, Bishnoi D, Badaruddoza. Effect of sex on prevalence of type 2 diabetes mellitus (T2DM) with respect to blood pressure, BMI and WHR among Punjabi population. *International Journal of Medicine and Medical Sciences*. 2010; 2(9):263-270.
29. Alam A, Siddiqui MA, Quamri MA, Fatima S, Roqaiya M, Ahmad Z. Efficacy of Spirulina (Tahlab) in Patients of Type 2 Diabetes Mellitus (Ziabetes Shakri) -A Randomized Controlled Trial. *Journal of Diabetes Metabolism*. 2016; 7(10). doi: 10.4172/2155-6156.1000710.
30. Shamsalinia A, Pourghaznein T, Parsa M. Relationship between Hope and Religious Coping among Patients with Type 2 Diabetes. *Global Journal of Health Science*. 2016; 8(1):208-216.
31. Rizwana AA, Sherwani AMK, Hafeel MHM. Prevalence of Ziabetes Shakari (Type 2 Diabetes Mellitus) and Dietary Habits among Senior Citizens Attending NIUM Hospital, Bengaluru. *International Journal of Advanced Complementary and Traditional Medicine*. 2015; 1(1):1-9.
32. Jitendra Varsakiya, Mandip Goyal. Life Style Intervention for Diabetic Patient in Ayurved, *Int. J. Ayu. Alt. Med*. 2015; 3(2):71-75.
33. Das KUK, Unnikrishnan AG, Jaykumar RV. 5th Edition: *Text Book of Medicine*. Jaypee Brothers Medical Publishers. 544-550
34. Mary G, Caroline H, Naomi H, Helen O, Lorraine O. Adult obesity and type 2 diabetes. *Public Health England*. 2014, 7.
35. Bosenberg LH, Van Zyl DG. The mechanism of action of oral antidiabetic drugs: A review of recent literature. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*. 2008; 13(3):80-88.