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Efficacy of Kanduri (*Coccinia indica*) in diabetes associated dyslipidemia - A randomized single blind standard controlled study

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Abstract

Background and objectives: Diabetes mellitus is characterized by elevated blood glucose, it can lead to serious vascular complications with poor prognosis. Dyslipidemia secondary to DM is one of the aggravating risk factors for cardiovascular diseases. In the Unani system of medicine, Diabetes associated Dyslipidemia has been treated with several potent anti-hyperglycemic and anti-dyslipidemic single drugs. To evaluate the effect of Kanduri (*Coccinia indica*) among patients of Dyslipidemia associated with type II Diabetes mellitus, this study was conducted.

Methods: A single blind, randomized, standard control clinical trial on patients of Dyslipidemia secondary to 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. The test group received 7.5 gram powder of dried leaves of Kanduri and the 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 TC, TGL, LDL, HDL were found insignificant, applying 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 with $p > 0.05$.

Interpretation & Conclusion: This comparative trial revealed that interventions of both groups have no effect on Dyslipidemia associated with DM type II, however, both the drugs were found to be free from any adverse effects.

Keywords: Diabetes associated dyslipidemia, *Kanduri*, *Coccinia Indica*

Introduction

Dyslipidemia is one of the major risk factors for cardiovascular disease in Diabetes [1]. It is well-established that dyslipidemia is a major risk factor for macrovascular complications in patients with type-2 diabetes mellitus (T2DM) and affects 10%-73% of this population [2, 3]. The characteristic features of diabetic dyslipidemia are high plasma triglyceride concentration, reduced high density lipoprotein cholesterol (HDL-c) concentration, and increased concentration of small dense LDL particles [4]. Early detection and treatment of dyslipidemia in type-2 diabetes mellitus can prevent risk for atherogenic cardiovascular disorder [5]. Metformin treatment improves weight and dyslipidemia in children with metabolic syndrome [6]. In the Unani system of medicine, various single and compound drugs have been described for the treatment of dyslipidemia and diabetes [7, 8]. Some of the herbs like Luk (*Laccifer lacca*), Zeera (*Carum carvi*), Gurmar Booti (*Gymnema Sylvester*), Tukhm Jayat (*Withania coagulans*), Post Kachnal (*Bauhinia variegata*), Darhald (*Berberis aristata*), Tukhm Methi (*Trigonella foenum graecum*), Kanduri (*Coccinia indica*), Tahlab (*Spirulina maxima*) etc. have been scientifically reported to have potent effects on properties like antioxidant, immunomodulator, antidiabetic, and antidyslipidaemic [9, 10].

Kanduri (*Coccinia indica*) is a climbing herb belonging to the family of Cucurbitaceae (Figures 1 and 2) [11]. Major chemical constituents of Kanduri are alkaloids, carbohydrate, proteins, amino acids, tannins, saponins, flavonoids, phytosterol, triterpenes, Heptacosane, cephalandrol, alkaloids, Cephalandrine A and B [12].

It showed significant triglycerides and cholesterol lowering effects among Dyslipidemic patients [13-17].

The reason behind preferring Metformin SR as a standard control is of great importance because it shares similar actions as the trial drug such as hypoglycemic, cardioprotective, nephroprotective, anti-dyslipidemic effect etc. [18, 19].

Material methods

This study was conducted to evaluation of the effect of Kanduri (*Coccinia indica*) in patients of Dyslipidemia secondary to Diabetes mellitus type 2, 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 test 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 case of diabetes with history of mild to moderate Dyslipidemia, Total Cholesterol < 250 mg / dl, Triglycerides < 499mg / dl (High), LDL < 140 mg / dl, HDL < 40–70 mg / dl, Patients between 35-60 years of age, Both gender, Normotensives (< 130/ 80 mm of Hg).

Exclusion Criteria

Total Cholesterol > 250 mg / dl, Triglycerides > 499 mg / dl (High), LDL > 140 mg / dl, HDL>70 mg/dl, Pregnant & lactating mothers, History of any systemic illnesses, and hypertension >130 – 80 mm of Hg, History of any other disorders of metabolism.

Statistical analysis

Statistical analytical of the study data was carried out by

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 with $p>0.05$.

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. Test 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 Lipid Levels of baseline observation and at the end of 8th week with the mean differences is shown in Table-2. The baseline value of the Lipid levels (TC, TGL, LDL and HDL levels) were compared in both groups and found without any statistically significant difference between them. The test group is found to be insignificant in reduction with reference to the TC, TGL, LDL and HDL levels at the end of 8th weeks from baseline in Kanduri (Test group) group ($p>0.05$) and Control group (Metformin ($p>0.05$)). The mean reduction in the lipid levels at the end of 8th weeks showed in significant differences between test and control groups using 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



Fig 1



Fig 2

Fig 1-2: (Kanduri-*Coccinia indica*)

Table 1: Demographic Data

S No	Demographic	Test 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	

Table 2: Effect of Test Drug on Lipid Profile

	Groups	lipid		p value
		0 Day (Mean ±SD)	56 Day (Mean ±SD)	
TC	Test	190.111±32.574	184.444±29.446	0.2932
	Control	192.388±42.385	176.222±51.819	0.1839
	P Value	0.8576	0.5622	
TGL	Test	190.722±63.49	171.111±65.276	0.1084
	Control	186.111±80.762	165.777±69.799	0.1709
	P Value	0.931	0.6181	
LDL	Test	107.133±29.215	166.133±28.698	0.883
	Control	109.777±37.416	100.6±37.65	0.385
	P Value	0.8146	0.6232	
HDL	Test	44.833±9.357	43.222±6.227	0.512
	Control	45.888±6.516	41.388±11.617	0.158
	P Value	0.697	0.559	

Discussion

The most common pattern of Dyslipidemia in patients with type 2 diabetes patients is elevated triglyceride levels and decreased HDL cholesterol levels [20]. Diabetes is associated with a high risk of vascular disease (i.e. 2- to 4-fold greater risk than that of individuals without diabetes) [21]. Unani Attiba described various drugs for the management diabetes and diabetes associated symptoms [22-27]. In this trial there was no improvement seen in the lipid profile in both groups statistically but symptomatically the subjects were feeling better. In this materialistic world differences in social structure, psychic stress, obesity, hormonal imbalance and heredity are optimizing the growth of DM as a pandemic. Gupta R *et al.* [28] In this study one could see that although the standard as well as the test drug shared similar properties expected results could not be derived in the objective parameters even though the patients were feeling fine subjectively. This study shows that *Coccinia indica* can be thought of in cases where symptoms persist even after administration of known hypoglycemic agents as suggested by a trial conducted by Gupt P *et al* and Kurian R *et al.* [29, 30] at the Central Council for Research in Homoeopathy. the dose of the test drug which was equal to all the patients irrespective of the demographic data, subjective as well as objective parameters and finally the food diaries which the patients had filled and the word of the patients about the exercise, diet and compliance to medication were considered true hence, we could not assess their perseverance, thirdly, the history given by the patient is assumed to be true to the best of our knowledge be it the duration of illness, regular consumption of medications, their activities and a host of other things. The concept of treating the patients according to pharmacogenetics and pharmacokinetics is also gaining momentum so, in the near future, each patient is treated in a unique way and the concept of temperament (*mizaj*) which has been discussed by our *Atibbas* would become the most important entity for treating the disorders. In light of the above discussion as far as the study is concerned it may be concluded that the test drug is safe and effective in giving symptomatic relief to the patients which is the primary cause of worry in most of the patients.

Conclusion

Though several herbal drugs have been proved to be found effective as anti dyslipidemic in preclinical and clinical studies, but this study the effect of Kanduri reveals insignificant effect on Dyslipidemia associated with DM

type 2. Though, the herb had been in use since a long time for control of poly urea and reducing the viscosity of blood. The limitation of the study like small sample size and variation in the biochemical levels, diet and lifestyle of the subjects might have also been played a role in the outcome of the study.

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Conflict of Interest: Nil

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