Research Article
Use and Effectiveness of Unani Medicines as Adjunct Therapy in the Treatment of Diabetes Mellitus: A Cross-sectional Study

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Abstract

Background and Objectives: Unani medicine use is quite popular among diabetics as a sole or adjunct therapy; however, quantified information about its usage is lacking. Hence, present study was aimed to estimate its use and effectiveness as adjunct therapy in the treatment of diabetes mellitus. **Materials and Methods:** A cross-sectional study was undertaken among 484 diabetes patients at a primary health care centre of Bengaluru from January to December, 2018. Systematic random sampling method was employed to obtain the required sample size. Information from patients was collected through personal interviews by using a semi-structured questionnaire after obtaining their written informed consent. Treatment satisfaction questionnaire for medication (version 1.4) was used to measure the major dimensions of patient satisfaction with treatment. **Results:** A prevalence rate of 25.6% of Unani medicines use in diabetics was observed in the present study. Unani medicine use was significantly associated with religion and socioeconomic status; while it was independent of age, gender and clinical characteristics of patients. Its Usage was found to be better in various treatment satisfaction components like effectiveness, safety and overall satisfaction ($p = 0.001$). While conventional medicine use singly was more convenient than the combined usage of conventional and Unani medicines ($p = 0.01$). Glycated haemoglobin, fasting and postprandial blood glucose levels in Unani medicine users were found significantly lower than non-users with a p-value of 0.001, 0.032 and 0.036, respectively. **Conclusion:** A considerable proportion of diabetics use Unani medicines along with conventional medicine and their use is sufficiently effective and safe in controlling the glycemic level.

Data Availability: All relevant data are within the paper and its supporting information files.

INTRODUCTION

The epidemic proportion of diabetes has placed it at the forefront of public health challenges currently facing the world[1]. According to the World Health Organization report, the number of people with diabetes had risen[2] from 108 million in 1980-422 million in 2014. The International Diabetes Federation warned that, if these trends continue, by 2045, 629 million people will have diabetes[3]. In India, there were 65.1 million people with diabetes in 2013 and this number was predicted[4] to rise to 109 million by 2035. Moreover, a disturbing trend is that Indians develop diabetes on average 10 years earlier than their western counterparts[5]. Moreover, the disease is chronic and progressive; it implicates a substantial financial burden on the patient. The annual cost of healthcare incurred by diabetes in India was around[6] $38 billion in 2011.

The current treatment approaches for diabetes can be broadly divided into two categories: conventional medicine and complementary and alternative medicine (CAM). Dissatisfaction of patients with conventional medicine in obtaining the desired benefits leads to the increased use of CAM in an attempt to improve the outcome of their illness. In studies of CAM use by diabetics, the prevalence varies from 17-78%, depending on CAM definition and the study design[7]. A study in Kerala found that approximately 40% of patients with diabetes use CAM regularly, of which 30% used it along with modern medicines[8]. Similarly, a study from Uttar Pradesh reported a prevalence of 68% CAM use among diabetes patients[9].

In Unani System of Medicine (USM), diabetes (Greek origin) has long been recognized by the virtue of its clinical symptoms and has been described by a variety of names-dūlāb/dūlābiyya, Istisqa-i-amnās, mu'attisha, 'utāsh, dawwāriyya/dawāra, barkāriyya or 'Illat barkār, zalaq al-kulya and qaramīs. Several somatic and functional abnormalities have been implicated in the causation of diabetes, noticeable of which is weakening/insufficiency of quwwat mughayyira (the transformative faculty) of the body[10]. A large number of single and compound formulations have been mentioned by Unani scholars for the treatment of diabetes. The single drugs are *Tinospora cordifolia*, *Bambusa arundinacea*, *Nelumbo nucifera*, *Gymnema sylvestre*, *Syzygium cuimini*, *Punica granatum*[11] etc. and the commonly used formulations are *Qurse dhayabitus*, *Qurse tabasheer*, *Qurse dhayabitus kafoori*[12] etc.

Several clinical trials[13-15] conducted in recent years have also reported the efficacy of Unani medicines in controlling the blood glucose level. Despite that, so far, no study has been conducted to quantify their usage among diabetics. Estimation of Unani medicines usage and their effectiveness in the treatment of diabetes is important for the integration of the Unani system of medicine into mainstream medicine. Hence, the present study was designed to estimate primarily, the prevalence of Unani medicine use in diabetics and secondarily, the perceived benefits from its usage.

MATERIALS AND METHODS

Study design, setting and duration: A cross-sectional survey was carried out from January to December, 2018 at a primary health care centre located in hegganahalli (BBMP ward no. 71), of Bengaluru, India. This health centre was purposively selected due to its easy accessibility.

Study population: Study population comprises all the known cases of diabetes, above the age of 18 years, attending the outpatient clinic of the primary health centre during the study period. Patients below the age of 18 years and unwilling to participate were excluded from the study.

Sample size and sampling techniques: The computation of the optimum sample size was based on the equation[16]:

$$N = \frac{[Z^2 P(1-P)]}{d^2} \times \frac{d_{eff}}{R}$$

where, N is the sample size, Z is the level of confidence measure (Z = 1.96, for 95% confidence level), D is the margin of error, P is the expected prevalence of usage of Unani medicine, d_{eff} is the design effect between simple random sampling and other methods of sampling and R is the sample size was adjusted for the expected non-response to obtain the final sample size.

Sample size for this study comes out 484 (by assuming 95% confidence level, 5% margin of error and expected prevalence of 30% usage[17] of Unani medicines by diabetics with a response rate of 80% and a design effect of 1.2 for using other than simple random sampling).

Systematic random sampling technique was applied to obtain the desired sample size. The sampling interval (k) was calculated and it comes out 8.3 (~8). The sampling was started by selecting an element randomly from the sampling frame and then every kth element in the sampling frame was selected till the required sample size achieved.

Ethics and consent procedure: The study was started following approval of the study protocol by the Institutional Ethical Committee of National Institute of Unani Medicine, Bengaluru vide IEC No.: NIUM/IEC/2016-17/017/TST/02. Permission was also taken from the concerned authorities of primary health centre. Written consent was obtained from each participant after explaining the purpose, method and procedures of the study. Respondents were informed that they could choose to or not to participate in the study. Only after they agreed to participate in the study, they were asked to sign the informed consent form and in the case of illiterate persons, their thumb impression was taken. The respondents were informed that all responses would be noted down but would be kept confidential at all times. Privacy was ensured during the interview.

Method of data collection: The data was collected through a face-to-face interview with each patient using a semi-structured questionnaire. Participants' were interviewed in the language in which they were most familiar with (Hindi, Kannada or English). If any patient was incapable of responding then family member was allowed to answer on behalf of the patient.

Survey instrument: A questionnaire was used to gather patients' socio-demographic information, clinical characteristics, use of Unani medicine in the treatment of diabetes and satisfaction with its usage. Questionnaire comprised of two main parts: Part 1 and 2. Part 1 consisted of 24 questions, 10 on demographic characteristics, 6 on diabetes-specific information and 8 on usage of Unani medicine.

Part 2 is a Treatment Satisfaction Questionnaire for Medication (TSQM, Version 1.4)[18], which is a valid measure of major dimensions of the patient's satisfaction with medication. It consists of 14 questions subdivided into 4 domains; effectiveness (questions 1-3), side-effects (questions 4-8), convenience (questions 9-11) and overall satisfaction (questions 12-14). The domain score was computed by adding the score of questions representing the specific domain called as composite score[19]. TSQM scale scores range from 0-100.

Blood glucose level measurement: Patients were enquired about their recent blood glucose levels and were asked to show the recent blood glucose reports at the time of interview. Blood glucose reports of up to 15 days prior to survey were taken into consideration.

Data processing and analysis: Data was collected under four pre-determined broad categories: demographic characteristics, clinical characteristics, Unani medicines use and perceived benefits from its usage. To ensure the quality of the data, each completed questionnaire was manually checked for completeness and consistencies before it was tabulated in Microsoft excel. SPSS version 20 and Epi Info 7 were used to calculate the descriptive and analytical statistics. Estimation of Unani medicines usage by diabetics was done. Besides, perceived benefits from their use in the treatment of diabetes were determined by comparing the TSQM scale scores and glycemic level of users and non-users using the Mann Whitney U test. Association between socio-demographic and clinical characteristics as predictors with Unani medicines use as dependent variable was also determined by using the chi-square test.

RESULTS

Socio-demographic characteristics: Table 1 provides information on the socio-demographic profile of respondents. A total of 484 diabetes patients were included in the present study. Mean age of them was 54.3±11.5, 61.8% of them were females and remaining were males. Majority of respondents were Hindus (70.9%) followed by Muslims. Most of the respondents (68.8%) were from the upper lower class, followed by the lower middle and lower class.

Table 1: Socio-demographic characteristic of respondents (n = 484)

Variables	Frequency	Percentage
Age (years)		
18-27	5	1.0
28-37	23	4.8
38-47	104	21.5
48-57	162	33.5
58-67	128	26.4
$\geq$68	62	12.8
Mean age	54.3±11.5	
Gender		
Male	185	38.2
Female	299	61.8
Religion		
Hindu	343	70.9
Muslim	138	28.5
Christian	03	0.6
Socio-economic status		
Upper middle	20	4.1
Lower middle	78	16.1
Upper lower	333	68.8
Lower	53	11.0

Table 2: Clinical characteristics of respondents (n = 484)

Variables	Frequency	Percentage
Duration of diabetes		
1-6 years	347	71.7
7-10 years	102	21.1
>10 years	35	7.2
Current diabetes medications		
Oral hypoglycaemic agents	444	91.7
Insulin only	10	2.1
Insulin+Oral hypoglycaemic agents	30	6.2
Diabetic complications		
Present	102	21.1
Absent	382	78.9
Type of complications (n = 102)		
Peripheral vascular diseases	8	7.8
Neuropathy	28	27.5
Retinopathy	35	34.3
Ischaemic heart diseases	14	13.8
Cerebrovascular accident	9	8.8
Nephropathy	8	7.8

Table 3: Unani medicine usage by diabetes patients

Variables	Frequency	Percentage
Unani medicine use		
Users	124	25.6
Non-users	360	74.4
Users (n = 124)		
Present users	115	92.7
Past users	9	7.3
Duration of use among present users (n = 115)		
<1 year	25	21.7
1-3 years	25	21.7
4-6 years	65	56.6
***Reason of usage (n = 115)**		
Safer	85	73.9
More effective	72	62.6
Less costly	52	45.2
Easily available	56	48.6
Recommendation for usage		
Doctor	10	8.7
Another patient	14	12.2
Family members and friends	84	73.0
Others	7	6.1
Information to regular doctor about usage		
Yes	58	50.4
No	57	49.6
Reason for discontinuation among past users (n = 9)		
Inconvenient	8	88.9
Unable to control blood sugar level	1	11.1

*Multiple responses were reported

Clinical characteristics: Table 2 provides information on the clinical characteristics of respondents. In the majority of patients (71.7%) duration of diabetes was found to be between 1-6 years. A major proportion of patients (91.7%) were on oral hypoglycaemics, 6.2% on insulin plus oral hypoglycaemics and remaining were exclusively on insulin. Diabetes associated complications were present in 102 patients, which included mainly the neuropathy, peripheral vascular diseases, retinopathy and nephropathy.

Unani medicine usage: Table 3 provides information about the usage of Unani medicines by diabetics; which includes the duration of use, reason of use, recommendation for usage, discontinuation during use and if discontinued then reason thereof. Among the surveyed population, Unani medicine users were found to be 25.6%. Among these, 92.7% were present users and 7.3% used it in the past. In past users, the major reason for discontinuation was inconvenient to use. Majority of present users (n = 90) reported that they are using for more than 1 year. Safer to use was the main reason for its usage, reported by most of the users (73.9%); while other reasons reported for its usage were effectiveness, low cost and easy availability. The most common sources of information on Unani medicine were friends and family members (73%). Among the users, 50.4% informed their doctor about usage.

Factors associated with the usage of unani medicine: Table 4 shows the association of socio-demographic and clinical characteristics with the usage of Unani medicine. Significant association was found between religion ($\chi^2 = 20.53$, p = 0.001), socio-economic status ($\chi^2 = 10.79$, p = 0.013) and Unani medicine usage. No significant association was found with age, gender, duration of disease and presence of complications.

Perceived benefits with unani medicine usage: Table 5 provides a comparison of patients' satisfaction with treatment among Unani medicine users and non-users. Treatment satisfaction score in four domains (effectiveness, safety, convenience and overall satisfaction) were compared. On comparison, it was found out that combined use of Unani and conventional medicine scored better in the domain of effectiveness, side effects and overall satisfaction when compared to only conventional medicine use with a p-value of 0.001, 0.001 and 0.001 respectively. Convenience was scored better by only conventional medicine users when compared to Unani plus conventional medicine users (p = 0.01).

Comparison of glycemic level of unani medicine users and non-users: Table 6 provides a comparison of the blood glucose level of Unani medicine users and non-users. On comparison, it was found that glycated haemoglobin (HbA1c), fasting blood glucose and postprandial blood glucose levels were lower in Unani plus conventional medicine users than only conventional medicine users with a p-value of 0.001, 0.032 and 0.036 respectively; while difference in the random blood glucose level was found statistically insignificant (p = 0.718).

Table 4: Association of socio-demographic and clinical characteristics with Unani medicine usage

	Total respondents (n = 484)	Users (n = 124)		Non-users (n = 360)			
Characteristics		Number	Percentage	Number	Percentage	χ^2	p-value
Age (years)							
18-27	5	0	0.0	5	100.0	9.41	0.094
28-37	23	4	17.4	19	82.6		
38-47	104	25	24.0	79	76.0		
48-57	162	54	33.3	108	66.7		
58-67	128	27	21.1	101	78.9		
$\geq$68	62	14	22.6	48	77.4		
Gender							
Male	185	56	30.3	129	69.7	3.39	0.065
Female	299	68	22.7	231	77.3		
Religion							
Non-Muslims	346	69	19.9	277	80.1	20.53	<0.001*
Muslims	138	55	39.9	83	60.1		
Socio-economic status							
Upper middle	20	11	55.0	9	45.0	10.79	0.013*
Lower middle	78	16	20.5	62	79.5		
Upper lower	333	86	25.8	247	74.2		
Lower	53	11	20.8	42	79.2		
Duration of diabetes							
<1 year	129	25	19.4	104	80.6	7.832	0.098
1.1-3	107	25	23.4	82	76.6		
4-6	111	37	33.3	74	66.7		
7-10	102	25	24.5	77	75.5		
>10 years	35	12	34.3	23	65.7		
Diabetes complications							
Present	102	30	29.4	72	70.6	1.78	0.323
Absent	382	94	24.6	288	75.4		

Test applied: Chi-square test, *p<0.05 considered significant

Table 5: Comparison of patients' satisfaction between users and non-users of unani medicine

	Users	Non-users	**Significance	
Domains	Median (Q1, Q3)	Median (Q1, Q3)	U-value	p-value
Effectiveness	83 (66.7, 83)	50 (33, 55.37)	5432.0	<0.001*
Side-effects	0 (0, 0)	25 (0, 44)	11694.0	<0.001*
Convenience	67 (67, 83)	83 (67, 83)	19012.0	0.011*
Overall satisfaction	91.6 (67, 92)	42 (33, 58)	4994.5	<0.001*

**Significance tested by Mann Whitney U test, *p<0.05 considered significant

Table 6: Comparison of blood glucose level between users and non-users of Unani medicine

	Users	Non-users	**Significance	
Laboratory values	Median (Q1, Q3)	Median (Q1, Q3)	U-value	p-value
HbA1c (glycated haemoglobin)	6.95 (5.97, 8.85)	9.9 (7.25, 13)	1158.000	<0.001*
FBS (fasting blood sugar)	151 (111, 206)	178 (121.5, 178)	6423.000	0.032*
PPBS (postprandial blood sugar)	225 (182.5, 299)	250 (189.75, 335.25)	6185.000	0.036*
RBS (random blood sugar)	200 (144, 255.25)	200 (149.5, 287)	5885.500	0.718

**Significance tested by Mann Whitney U test, *p<0.05 considered significant

DISCUSSION

A prevalence rate of 25.6% of Unani medicines use in diabetics was observed in the present study which is relatively similar to studies conducted by Monica *et al*.[17] and Vishnu *et al*.[8], who reported the prevalence of 29 and 30% complementary and alternative medicine (CAM) use in diabetics respectively; while it is much lesser than other similar studies conducted by Kumar *et al*.[9], Roy *et al*.[20] and Bhalerao *et al*.[21], which showed an approximately 65% CAM use. However, the results of other studies are not directly comparable with this study because of differences in the definition of CAM use. In the present study, we had enquired about only the Unani medicine usage in diabetics. At present

no published data is available about the prevalence of Unani medicine use in diabetes patients. Hence, the findings of present study have been compared with the studies on CAM use in diabetics.

In the present study, a considerable proportion of diabetics reported the Unani medicines usage along with allopathic treatment. The proposed reason for the increased utilization of Unani medicines may be the dissatisfaction of patients with conventional medicine in effectively managing the underlying problem and the perception that Unani medicine usage will improve the outcome of their illness without causing any harm.

The main sources of information for diabetes patients about Unani medicine were friends and family members. These findings are in agreement with the results of Saudi study in which the source of information about CAM were mainly friends and relatives[22]. This finding highlights the importance of patients' close environment in the decision-making process for obtaining medical care.

Safer to use was the most common reason for using Unani medicine as reported by most of the users. Other reasons stated for using Unani medicine were effectiveness, low cost and its easy availability. These findings are in line with the findings of the study conducted by Sadiq *et al.*[23].

In the present study, the majority of patients informed their doctor about Unani medicine usage along with allopathic medicine. This finding is in contrary to the studies conducted by Huri *et al.*[24] and Agrawal and Goel[25], which reported the disclosure rate of 20 and 39%, respectively. Better doctor-patient communication may be the probable reason for higher disclosure rate in the present study.

This study showed that only a few patients had discontinued the Unani medicine use and the main reason for discontinuation was an inconvenience in its use. This is in contrast with the finding of a study conducted by Huri *et al.*[24], where most of the patients discontinued the use without a valid reason. This finding highlights the issue of large dose and dosage forms of Unani medicines. Hence, these drugs may be given in such doses and dosages form so that its use becomes convenient for patients.

Unani medicines use was significantly associated with religion and socio-economic status; while it was independent of age and gender. These findings are in line with the finding of studies conducted by Naja *et al.*[26] and Ching *et al.*[27], which also reported significant relationship of CAM usage with religion and insignificant association with gender and age. Contrary with our study findings Kumar *et al.*[9], reported that religion was not associated with the usage of CAM in patients with diabetes.

In the present study, no significant association was found between duration of diabetes, presence of complication and Unani medicine usage. This finding was consistent with a study conducted by Manya *et al.*[28], who reported that the duration of diabetes was not associated with CAM use in diabetics. In contrast, Naja *et al.*[26] reported that the duration of diabetes was associated with CAM use. Significant association was found between the presence of complications and Unani medicine usage in previous studies conducted by Bhalerao *et al.*[21] and Khalaf and Whitford[29]. The statistical insignificance in the present study might be due to the lesser percentage of Unani medicine users in comparison to other studies.

Unani medicine use was found to be better by diabetics in most of the aspects like effectiveness, safety and overall satisfaction while conventional medicine use singly was found to be more convenient than the combined usage of conventional and Unani medicines. This finding is in accordance with the study conducted by Monica *et al.*[17]. Unani medicine users reported that its usage was sufficiently effective in reducing their glycemic levels. This claim of the patients was also verified by comparing the values of glycated haemoglobin, fasting, postprandial and random blood glucose levels of users and non-users. On comparison, the glycemic level was found significantly lower in users when compared to non-users. This attested the claim of patients that Unani medicines along with conventional medicine are more effective in controlling the blood glucose level. Users also reported that their usage did not cause any side-effects. This highlights that Unani medicines are safe to use along with conventional medicine. However, these claims were not verified by any objective parameter. Overall satisfaction in Unani medicine users seems to be related to the effectiveness of these medicines in the treatment of diabetes without causing any adverse effects. Lower convenience scores in Unani medicine users may be because of large doses of Unani medicines as compared to conventional medicine and secondly, these drugs are given in the form of decoction, infusion which is time-consuming[30] when compared to readily administer oral hypoglycemics.

The strength of the current study is in it being the first of its kind in India to estimate the use and effectiveness of Unani medicines as adjunct therapy in the treatment of diabetes. However, the study was confined to the diabetes patients of a selected health centre of an urban locality of Bengaluru. The findings do not represent the practices prevalent in the general population. Accordingly, these results may not be generalized to a broader population of diabetes patients in other parts of the city.

The findings of the study provide sufficient evidence for advocating the use of Unani medicine in patients with diabetes along with conventional drugs for better control of blood sugar level and it is safe to use as perceived by patients.

Further community-based studies are needed to investigate the actual usage pattern of Unani medicines by diabetics. Several other factors like associated co-morbidity, measurement of hypoglycaemic episodes that were not taken in the present study should be addressed in subsequent studies.

CONCLUSION

It can be inferred from these results, that a considerable proportion of diabetes patients uses Unani medicine as a complement to their conventional medicine. Unani medicine was more prevalent in Muslim patients and those belonging to low socio-economic group; while, it was independent of age, gender and clinical characteristics of patients. Furthermore, the study finds that Unani medicine use along with conventional medicine is sufficiently effective in controlling the glycemic level and safe to use as perceived by patients. However, its use was a little bit inconvenient to users in comparison to only conventional medicine use.

SIGNIFICANCE STATEMENT

The current study is in it being the first of its kind in India to examine the prevalence and perceived benefits by Unani medicine use among diabetic patients. The findings provide sufficient evidence for advocating the use of Unani medicine in patients with diabetes along with conventional drugs for better control of blood sugar level.

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