

**PATTERNS AND DETERMINANTS OF COMPLEMENTARY AND ALTERNATIVE MEDICINE USE AMONG TYPE 2 DIABETIC PATIENTS IN A DIABETIC CENTER IN SAUDI ARABIA: HERBAL ALTERNATIVE USE IN TYPE 2 DIABETES**

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**ABSTRACT**

**Background:** Despite of the notable advances in the conventional treatment of diabetic patients, use of complementary and alternative medicine is increasing (CAM), due to unsatisfactory results or adverse effects of the conventional treatment. The unsupervised use of the (CAM) may increase the risk of misuse. Due to observed wide use of (CAM).

**Aim and Objectives:** The current study aim at determining the prevalence, patterns, and predictors of complementary and alternative medicine (CAM) use in patients with type 2 diabetes mellitus (T2DM).

**Methods:** Through a cross-sectional design, we select a random sample of 310 adult patients with T2DM registered at Jeddah Diabetic Center (JDC), Jeddah, Saudi Arabia JDC over the year 2016. A semi-structured questionnaire was used to collect data regarding the use, frequency, and duration of use of a list of common herbals such as black seed (*Nigella sativa*), ginger, cinnamon, etc.; and users' attitude and belief towards CAM use in T2DM. In addition, socio-demographic, and clinical factors were collected and analyzed as factors and predictors for CAM use.

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**Results:** Eighty (25.8%) participants declared using CAM to treat diabetes, including ginger (11.6%), black seeds(10.0%), cinnamon (5.5%), fenugreek(2.9%),garlic (2.9%) and green tea (2.3%),while<1% used myrrh, onion or Asafoetida.Twenty-seven (8.7%) participants used more than one herbal. Majority of the users used herbal on a daily basis, buying it from a perfumery, and were advised by their friends. Majority of CAM users believed that CAM use improves health (96.3%), controls blood sugar (96.3%) and has fewer side effects (95.0%).Older age and being a female were significant predictors of CAM use.

**Conclusion:** One in four diabetic patients attending JDC isa regular userof herbal medicine for diabetes. Most frequently used herbals are ginger, black seed, and cinnamon. Majority of users believe that herbal products are safe and effective in treating diabetes.

**Keywords:** Complementary and alternative medicine, herbal medicine, ginger, black seed, *Nigella sativa*, cinnamon

## INTRODUCTION

Recent progress in the treatment of type 2 diabetes mellitus (T2DM) including pharmacological treatments and lifestyle management achieved greater therapeutic success. This advancement enabled rigorous glycemic targets and comprehensive management of adjacent metabolic disorders and comorbidities.<sup>1</sup> Tremendous research has explored a multitude of pharmacological approaches and multi-approach protocols thereby targeting key pathophysiological disorders present in T2DM to enhance insulin sensitivity in implicated organs, without inducing insulin hypersecretion responsible for severe hypoglycemia.<sup>2-4</sup> This resulted in remarkable improvement in the efficacy and safety of preventive and therapeutic interventions against diabetes.<sup>3,5</sup>

Despite remarkable advance in the conventional treatment, use of complementary and alternative medicine (CAM) such as herbal medicine and other traditional healings is increasing among T2DM patients due to unsatisfactory therapeutic results or adverse effects that persist with conventional treatment.<sup>6-8</sup> It has been reported that 24% to 71% of the patients are using CAM in Saudi Arabia; and in developed countries such as Australia, France, and the USA, this proportion reaches almost 50% of the general population.<sup>8-11</sup>

Over 400 types of herbals and plant remedies have been used in diabetes across different societies and civilizations.<sup>12-14</sup> In Saudi Arabia, the use of herbal medicine is a mixture between the cultural heritage of the Eastern and Middle-Eastern civilizations including traditional Chinese herbalism, Ayurvedic herbals; the traditional Arabic and Islamic medicine gaining remarkable success is expanding its use to the rest of the world.<sup>15,16</sup>

The expansion of use of CAM is promoted primarily by the media or via social networks in the form of family or friends' advice. Thus, it is often unsupervised by the healthcare providers.<sup>17</sup> This results in insufficient knowledge and awareness about the effects of herbal products, which may lead to several misconceptions and increase the risk of misuse.<sup>18</sup> In addition, prescribers should be aware whether their patients are taking CAM in addition to the conventional treatment, in order to take into account possible pharmacological interactions that might occur with herbals.<sup>19</sup>

Providing an insight on the magnitude and the pattern of use of CAM among diabetic patients will help to supervise this practice and deliver appropriate answers to further patients' interrogations. Furthermore, this paves the way for research on eventual efficacy and safety of the identified products.

*Subjects and methods:* A cross-sectional study was conducted between 1 November 2016 and 31 December 2016, at Jeddah Diabetic Center (JDC), Jeddah, Saudi Arabia. Being a governmental referral center, JDC serves approximately 8,000 diabetic patients and provides therapeutic and preventive medical care with a comprehensive approach. Inclusion criteria were applied as follows: adult patients (age > 18 years) following for type 2 diabetes at the JDC in the year 2016. Exclusion criteria were applied as follows: other types of diabetes, children aged ≤ 18 years, pregnant women, and mentally disabled patients. The sample size (N=310) was calculated to detect an expected 30% prevalence of CAM use, with 5% margin error and 80% statistical power, among a total population of 8,000. A simple random sampling was used to include 10 eligible patients per day, among those attending the JDC during the study period, until reaching the target sample size.

A semi-structured questionnaire was used to collect data. It was divided into 5 parts: part 1) socio-demographic and economic data such as age, gender, marital status, monthly income, educational level, etc.; part 2) clinical data including assessment of diabetes, past medical history and comorbidities and lifestyle factors; part 3) assessment of herbal medicine use, duration, frequency, and pattern of use of 9 herbal products including: black seed (*Nigella sativa*), ginger (*Zingiber officinale*), cinnamon (*Cinnamomum verum*), asafoetida (*Ferula assafoetida* L), fenugreek (*Trigonella foenum-graecum*), green tea (*Camellia sinensis*), myrrh (*Commiphora myrrha*), garlic (*Allium sativum*) and onion (*Allium cepa* L.). Supply source, knowledge source, and monthly expenditure were investigated, as well as whether participant discontinued or reduced the conventional treatment; part 4) attitude and beliefs towards CAM including usage purpose, perceived effects, and side effect; and part 5) compliance with conventional treatment using Morisky Medication Adherence Scales (MMAS-4), which is a

validated tool assessing self-reported medication adherence.<sup>20</sup>The study protocol was ethically approved by the Department of Medical Research and Studies, Directorate of Health Affairs, Jeddah, Ministry of Health.

Statistical analysis was carried out using SPSS, version 21 (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp. 2012). Descriptive statistics were used to present participants' demographic and clinical characteristics, as well as the patterns of CAM use and answers to the different items of the questionnaire. Continuous data were presented as mean±standard deviation (SD) and categorical data were presented as frequency (percentages). Analytical statistics were used to study the significance of socio-demographic and clinical factors on CAM use; as well as the impact of CAM use on compliance and attitude towards conventional treatment. Comparison of proportion was carried out using chi-square test or Fisher's exact test; while comparison of means used independent t-test or One-Way Analysis of Variance (ANOVA), as appropriate. Binary logistic regression was carried out to analyze predictors of CAM use. A p-value <0.05 was fixed to reject the null hypothesis.

## MAIN RESULTS

Of the 310 diabetic patients, 75.2% were males; mean±SD age=57.58±8.50 years, 96.5% were married. Majority of the participants were highly educated, with university qualifications (41.6%) or post-graduate degrees (6.8%). Regarding social class, 70.0% live in apartments and 61.3% own their residency; and 43.2% had monthly income <5,000 SAR (US\$1,350) [Table 1]. Two thirds of the cases (64.8%) were diagnosed since 5-10 years ago. Most of the cases were on oral hypoglycemic(81.8%), while 30% on insulin and 45.5% were on diet. Medication adherence showed that 12.3% of participants had low, 75.8% had medium and 11.9% had high MMAS-4 score.76.7% of the cases reported that they attendthe diabetes clinic at least four times annually; whereas only 18.1% used to check their blood sugar at home ona daily base, and 57.1% on a weekly base. The commonest reported complications includedneuropathy (48.7%), retinopathy (22.9%) and hyperglycemia (21.9%).

Eighty (25.8%) participants declared using herbal medicine to treat diabetes; includingginger (11.6%), black seed (10%), cinnamon (5.5%), fenugreek (2.9%), garlic (2.9%), and 2.3% used green tea; while <1% used myrrh, onion or Asafoetida. Food supplement was used by 30.6% of the participants which includedVitamin B complex (15.2%), Vitamin D (14.5%), calcium (0.6%), and omega 3 (0.3%) (Table 3). The majority of the users have been using the herbal alternative daily for more than 1 year; and perfumery was their major supply source, where they spent<100SAR (<US\$27) per month (Tables 4 &5).Most of the users believe that

herbal alternative improves health (96.3%), controls blood sugar (96.3%), and has fewer side effects (95.0%) (Figure 1).

Table 6 shows that females constituted a significantly higher proportion of the users than the non users of the herbal alternatives (40% versus 19.6%;  $p=0.0003$ ) and the users were significantly older than the non users (mean $\pm$ SD age=59.60 $\pm$ 6.76 versus 56.87 $\pm$ 8.93 years;  $p=0.013$ ). Otherwise, no statistically significant difference was observed regarding educational level or other socioeconomic factors. Compared to the non users, the users were more likely to assess their blood sugar daily (23.8% versus 16.1%;  $p=0.009$ ), and less likely to have >1 comorbidity (45.0% versus 62.2%;  $p=0.028$ ) or diabetes complications including neuropathy (35.0% versus 53.5%;  $p=0.004$ ) and hyperglycemia (0.0% versus 29.6%;  $p<0.001$ ). Else, the 2 groups were similar regarding duration of T2DM, treatment regimen, attendance to diabetes clinic visits, prevalence of retinopathy and hypoglycemia. In both univariate and multivariate regression models, older age and female gender were significant predictors for herbal alternatives use among diabetic patients. Results of univariate and multivariate regression analysis are depicted in Table 7.

## DISCUSSION

This study provided information about herbal medicine use among T2DM patients attending JDC, one of the main specialized centers for diabetes care in the Western region of Saudi Arabia. It showed that approximately one in four patients (25.8%) is a regular user of herbal medicine for therapeutic purpose against diabetes along with the conventional treatment. The most frequently used herbs were ginger, black seed and cinnamon; and less frequently used herbs were fenugreek, garlic, and green tea.

Reports from local, regional, and international studies showed a wide range of prevalence of use of CAM. Locally, higher prevalence of CAM use was reported by Al-Eidi et al., who found 30.5% of CAM users among T2DM patients.<sup>21</sup> In a more specific context, Bakhotmah and Alzahrani reported 52.9% of topical CAM products use among patients with diabetic foot complications.<sup>22</sup> Two other authors investigated CAM use among type 1 and T2DM patients, and found lower prevalence of use. Alghothamy et al., found 24.6% of CAM users among a series of 228 type 1 and T2DM patients<sup>23</sup>; while Al-Rowais et al., found 17.4% among 296 type 1 and T2DM patients, which is the lowest prevalence reported in Saudi Arabia.<sup>8</sup> Regionally, CAM use among T2DM patients was as frequent as 51.9% in Palestine<sup>24</sup> and 46.0% in Bahrain<sup>25</sup>, followed by 38.1% in Lebanon<sup>26</sup>; and 34.6% among type 1 and T2DM patients in Turkey.<sup>27</sup> Internationally, the prevalence of use of CAM ranged between

29.0% in Australia, and 33.0% to 35.0% in Guinea<sup>28</sup>, Austria<sup>29</sup> and in the USA<sup>10,30</sup> to 62.5% in Malaysia.<sup>31</sup>

In the present study, ginger was the most frequently reported herbal used by 45.0% of herbal medicine users on a daily basis in the majority of the cases. Ginger is widely used as a cooking spice in several culinary traditions such as in the Middle-Eastern culture.<sup>32</sup> It is also used as a natural remedy for various diseases and pathological symptoms<sup>33</sup>, besides observed efficacy in diabetes.<sup>34-36</sup>

Black seed was the second most frequently reported herbal used by 38.8% of herbal medicine users, on a daily basis in majority of cases. It is considered as one of the iconic prophetic medicinal traditions, as it was recommended by Prophet Mohammed (Peace been Upon Him) and described as being “a cure for every disease except death”.<sup>37</sup> It is used in the form of seeds, powder or oil, and nowadays capsules containing black seed extracts are available in the market. A considerable number of researches published on various therapeutic effects of black seed extracts, including antioxidant, anticancer, analgesic, antimicrobial, antihypertensive, cognitive enhancing, anxiolytic, and immunomodulatory properties,<sup>38-42</sup> besides anti-diabetic properties.<sup>43</sup> Cinnamon was the third most frequently used herbal in this study.

In contrast to this study, several national and international studies investigated a wider range of CAM types besides herbals such as nutrition supplements, spiritual healings, relaxation, energy systems, etc. However, herbal medicine was often reported as the most frequently used type, although the most frequent herbals differed from one study to another study. In local studies, Al-Rowais et al., reported myrrh, black seed and asafoetida as the top 3 herbs<sup>8</sup>; while Algothamy et al., reported fenugreek, black seed and myrrh<sup>23</sup>, and Bakhotmah and Alzahrani reported honey, myrrh and black seed.<sup>22</sup> Regionally and in Asian countries, garlic, bitter melon (*Momordica charantia*) and cinnamon were the three preferred herbals in Bahrain;<sup>25</sup> fenugreek seeds, rosemary (*Rosmarinus officinalis*), and olive in Palestine;<sup>24</sup> and gourd (*Momordica Charantia*), Misai Kuching (*OrthosiphonStamineus, Benth*) and garlic in Malaysia.<sup>31</sup> In Australia, the most frequently used CAM types were multivitamins, followed by cinnamon, prayers, and coenzyme q10; while other herbals included garlic, fenugreek and American Ginseng.<sup>9</sup> In Europe, the most frequent types of CAM used were nutrition supplements including vitamins, followed by minerals and multivitamins; and herbals.<sup>29</sup> In the USA, herbal use was minor compared to prayer and spiritual healings, which was the predominant alternative healing practice among diabetic patients.<sup>30,44</sup> Spiritual healing and prayers were not investigated in this study, as this study focused on herbals. In a conservative

and religious country as Saudi Arabia, spiritual healings and prayer are undoubtedly a very prevalent healing recourse in all type of medical complaints.<sup>45</sup>

In this study, herbal medicine users were mostly females and relatively older compared with nonusers; and both were significant predictors for CAM. Literature review by de Souza et al., demonstrated that the use of CAM is more common among the elderly compared to the young population; highlighting the necessity for healthcare providers to systematically ask their patients about such usage, avoid eventual pharmacological interactions.<sup>19</sup> Otherwise, users and nonusers were comparable regarding educational level and socioeconomic class suggesting that the use of CAM is more likely related to cultural factors rather than affordability. Comparably, other local studies showed that the use of herbal alternatives was associated with other demographic factors such as low educational level<sup>18</sup> and unemployment.<sup>21</sup> Regarding clinical factors, herbal users exhibited relatively better health status including less comorbidities and diabetes complications, especially neuropathy and hyperglycemia compared to the nonusers. It is difficult to attribute these differences to herbal use, using the current study design as the general health status may be in relation with other factors such as patient's attitude and lifestyle. In addition, herbal users were more likely to be involved in self-care which was indicated by regular (daily or weekly) home blood measurement; which was frequently observed by users than nonusers.

This study is limited by recall bias impeding collection of data about further herbal products used by the participants; besides the ones listed in the questionnaire.

## CONCLUSIONS

One in four diabetic patients attending JDC is regular user of herbal medicine for diabetes. The most frequently used herbals are ginger, black seed, and cinnamon. Except female predilection and older age, no other notable demographic factor is distinctive among herbal users. Most of users believe that herbal alternatives improve health, control blood sugar and have fewer side effects, and were encouraged to use CAM by their family or friends. It appears that the patient environment and cultural background are the major determinants for use and the product choice. A subsequent paper will attempt to retrospectively study the impact of CAM use on glycemic control and metabolic profile on the present population.

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## AUTHOR DISCLOSURE STATEMENT

Authors declare having no actual or potential conflict of interest in connection with the present manuscript.

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