Journal of Pharmaceutical Research International

32(2): 67-72, 2020; Article no.JPRI.55301
ISSN: 2456-9119
(Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

Diabetics' Views Concerning the Safety and Efficacy of Herbal Medicines: A Qualitative Study

Saud M. Alsanad[1*]

[1]Department of Pharmacology, College of Medicine, Imam Mohammad Ibn Saud Islamic University (IMSIU), Riyadh 13317-4233, Saudi Arabia.

Author's contribution

The sole author designed, analysed, interpreted and prepared the manuscript.

Article Information

DOI: 10.9734/JPRI/2020/v32i230406
Editor(s):
(1) Rahul S. Khupse, University of Findlay, USA.
Reviewers:
(1) Salwa Refat El-Zayat, National Research Centre, Cairo, Egypt.
(2) Selami Selvi, Balıkesir University, Turkey.
Complete Peer review History: http://www.sdiarticle4.com/review-history/55301

Original Research Article

Received 28 December 2019
Accepted 05 March 2020
Published 13 March 2020

ABSTRACT

Introduction: Diabetics have been known as potential to consume herbal and dietary supplements (HDS) to control their diabetes. HDS are taken widely despite limited scientific evidence of their safety and efficacy.
Methods: This qualitative study aimed to shed light on diabetic patients' experiences and perceptions of HDS to identify any perceived benefit or harm.
Results: The findings provided two main themes concerning patients' experiences of HDS use: Perceived beneficial experiences and perceived harm experiences. Most patients indicated experiencing benefits from HDS use.
Conclusion: It is essential to understand patients' perceptions and appreciate their experiences in order to support them when choosing appropriate CAM treatments and avoid any harm resulting from their lack of knowledge or erroneous notions about such treatments. Many more pre-clinical and clinical studies are needed to examine the efficacy and safety of popular HDS.

Keywords: Complementary and alternative medicine; herbal medicines; dietary supplements diabetes mellitus; Saudi Arabia.

**Corresponding author: E-mail: smsanad@imamu.edu.sa, alsanads@gmail.com;*

1. INTRODUCTION

Herbal and dietary supplements (HDS) are taken widely despite limited scientific evidence for their efficacy. Studies have revealed that some HDS are useful for relieving symptoms of diabetes, as well as reducing the side effects of conventional treatment, improving quality of life, slowing disease progression, and reducing the risk of further disease arising. However, inappropriate HDS use could lead to serious complications, not only by reason of adverse events but also by interfering with conventional medicine [1].

It is difficult to accurately measure the extent of consumers' HDS use, especially in the unregulated and internet markets of HDS products. This might be because of the unreliability of methods used and, particularly, survey-based studies [2]. However, most studies concerning complementary and alternative medicine (CAM) use clearly show that herbal medicine is the most popular treatment in CAM practice, as well as in traditional medicine systems [3].

The World Health Organization (WHO) reported that about 70% to 80% of the world's population largely depends on herbal sources for their primary treatment [4]. This is in accordance with another report that traditional medicine derived from botanicals is used by 60% of the world's population [5]. In 1998, a UK survey found that about 20% of its participants used HDS and HDS sales in the UK increased by 50% from 1995-2000. Another UK study reported that HDS use was 28% in 1998, 20% in1999, and 26% in 2005 [6]. A systematic review of 87 studies investigating the prevalence of CAM among European countries found the prevalence of HDS varied from 5.9% to 48.3% [7]. In 2004 in the USA, HDS use was reported by 18.9% of the study's participants, representing a market of about $180 billion [8].

Some herbal medicines have been extensively studied and there is evidence of their potential benefits and risks. However, most of the information relates to their safety and efficacy when these herbs are examined as 'phytopharmaceuticals' and treated under conventional medicine protocols (i.e., under the supervision of healthcare professionals). This means few studies have been conducted to evaluate the efficacy and safety of herbal medicine and combinations of such medicine when used as self-medication or as recommended by herbal medicine practitioners. Therefore, it is possible to say that scientific evaluation of the efficacy and safety of herbal medicine as a treatment method has not yet been approached [9].

Diabetes mellitus (DM) is a complex chronic illness associated with hyperglycemia (high blood glucose level) resulting from defects in insulin secretion, insulin action, or both. There are two main types of diabetes mellitus; Type I diabetes (T1DM), formerly known as insulin-dependent diabetes mellitus, accounts for approximately 5% of all diabetic patients. T1DM is characterized by insufficient insulin production and requires daily insulin consumption. Type II diabetes (T2DM), previously called non-insulin-dependent diabetes mellitus, accounts for approximately 95% of all patients with diabetes. It results from the body's ineffective insulin use [4].

Diabetics have been known as potential consumers of HDS as a method of controlling their diabetes. A review of the literature suggests the prevalence of CAM use among diabetic patients ranges from 17% to 78% [10]. Studies revealed that about 45% of Saudi Arabia's diabetic population had used CAM [11]. Diabetic patients are 1.6 times more likely to use CAM than non-diabetics for several reasons [12] and the most widely used CAM treatments are HDS. It is estimated that over 400 HDS products have been reported worldwide as treatment options for diabetes [12,13]. Some herbs can help in controlling hyperglycemia in mild cases of non-insulin dependent diabetes. These include fenugreek (*Trigonella foenum graecum*), cinnamon (*Cinnamomum spp*.), bitter gourd (*Momordica charantia*), banaba (*Lagerstroemia speciosa*), goat's rue (*Galega officinalis*), Gymnema (*Gymnema sylvestre*), and black seeds (*Nigella sativa*) [14].

Therefore, given the issues associated with HDS, it is necessary to find an appropriate mechanism to provide safe use of HDS products for patients. This qualitative study aimed to shed light on diabetic patients' experiences and perceptions of HDS to identify any perceived benefit or harm.

2. METHODOLOGY

Semi-structured questionnaires were administered to participants at the Medical Services Centre, male clinics, at Imam Mohammad Ibn Saud Islamic University (IMSIU), Riyadh. Participants were above 18 years and

were receiving treatment for a diabetic diagnosis. The semi-structured questionnaires included open-ended questions to obtain in-depth views on HDS safety and efficacy.

The interviews were carried out by five trained year-four medical students from the College of Medicine at IMSIU. The students had been carefully trained on questionnaire administration and interviewing and had been involved in a number of questionnaire and interview studies. All respondents were interviewed at the Medical Services Centre at IMSIU. Interviews lasted from twenty minutes to around an hour. Before deciding to take part in the study, the participants were fully informed of the study's purpose and the nature of their participation. They were also asked to sign a consent form.

The interviews were recorded. The author then transcribed and analyzed the interviews using thematic framework analysis. The data analysis began by reading the data several times to gain a sense of understanding and see patterns and trends in the responses to develop conclusions. Then, the data were read word by word to derive codes by highlighting words that captured key thoughts or concepts. The next step was to note the first impressions and initial analysis. After that, the codes were classified into categories according to how they were related and linked [15,16]. The interviews were carried out in Arabic; however, the author translated the final transcripts into English. To validate the translation, a bilingual academician reviewed the translation.

3. RESULTS AND DISCUSSION

Twenty-five male diabetics were interviewed. The findings provided two main themes in relation to patients' experiences of HDS use: perceived beneficial experiences and perceived harmful experiences. These themes agree with other themes identified from previous studies. All patients' answers were coded (P1-P25). Most patients (18, 72%) indicated experiencing benefits from HDS use. Patients used different expressions to describe the beneficial outcomes obtained from HDS but most benefits cited could be classified under improving wellbeing, supporting the immune system, controlling glucose levels, relieving symptoms associated with diabetes, and controlling conditions and symptoms of other medical problems unrelated to their diabetes. The themes and codes that emerged from participants' answers are shown in Table 1.

This study confirmed that most patients expressed positive feelings and experiences regarding HDS use. They believed the HDS helped them and the main benefits reported were improving wellbeing, supporting the immune system, controlling glucose levels, relieving symptoms associated with diabetes, and controlling conditions and symptoms of other medical problems unrelated to their diabetes. In addition, patients believed that particular HDS helped them with specific problems; for example,

> *"All are lowering my blood glucose" (p 1).*
>
> *"All herb/dietary supplements were slightly lowering blood glucose and improving my mood" (p 2).*
>
> *"Appel cider helps sometimes to lower blood glucose" (p 4).*
>
> *"Because of grapefruit, bitter gourd, and green tea, I feel better" (p 7).*
>
> *"Guava leaf helps to control my glucose level" (p 12).*
>
> *"Onion lowers my blood glucose" (p 17).*
>
> *"Ginger lowers my blood glucose" (p 19).*
>
> *"Olive leave lowers blood glucose" (p 20).*
>
> *"Cinnamon lowers blood glucose" (p 21).*
>
> *"Peppermint, anise, and ginseng all helped me with the flatulence and abdominal pain" (p 23).*
>
> *"Black seeds, cumin, and pomegranate helped me with my abdomen pain" (p 24).*
>
> *"I always use olive oil, olive leaves, and green tea to control my blood glucose" (p 25).*

Some patients were certain that some HDS were 'better' than conventional medicines and helped them to treat their health problems.

> *"Because of black seeds, the glucose levels became controlled and I've stopped taking my conventional medicines" (p 8).*

"Cinnamon acts better than my diabetes medicine" (p 9).

"I believe cinnamon can totally cure my diabetes" (p 24).

Some patients did not experience noticeable benefits from using HDS but they considered them to be generally beneficial and that they might help to prevent their situation worsening. The extent to which diabetics expect to cure or alleviate their symptoms with HDS needs to be further explored.

"All mentioned herb/dietary supplements helped" (p 3).

"Because of all mentioned herb/dietary supplements, I feel better" (p 11).

"All herb and dietary supplements helped me" (p 13).

"All mentioned herb/dietary supplements kept me healthier" (p 18).

"I can't determine which herbs but I feel they helped to lower my blood glucose" (p 22).

Six patients in this study reported a neutral experience of HDS use, i.e., neither benefit nor harm. However, one patient indicated he had negative experiences while using HDS, although he was unsure whether HDS were the reason. He described the following reactions after taking HDS. Cinnamon was involved in the negative experiences, but it was also reported as beneficial HDS by other patients:

"Yes, I had a problem, but I am not sure if the herbs were the reason. However, there was a digestive problem" (p 16).

It has been argued that certain HDS may conflict with the effectiveness of conventional treatments or lead to unwanted side effects. Conversely, some HDS products have shown notable benefits for diabetes or in relieving the side effects of conventional treatments and improving patients' physical and emotional status [17]. Healthcare professionals are concerned about HDS use by diabetic patients as the use is increasing. Accordingly, many healthcare providers do not recommend HDS to their diabetic patients, which results in some patients concealing such information from their medical team [18]. Therefore, it is not always a solution to prevent patients from using HDS because of speculation or erroneous assessments for precautionary purposes, as it would exaggerate the problem. It would be useful if healthcare professionals checked whether their patients used HDS and assured them it was acceptable and understandable.

HDS use has often been considered as a threat to the health of diabetic patients. In contrast, growing evidence shows that some HDS may provide an opportunity for patient empowerment by giving patients a sense of control and improvement in wellbeing [19]. However, reports about harms or beneficial outcomes of CAM and, in particular, HDS remain inconsistent, considering that patients, as this study and others have indicated, are willing to use HDS and some strongly believe that HDS can really cure their diabetes.

In general, the regulation of HDS is complex because of the different ways in which countries define and categorize herbal preparations and dietary supplements. For example, in the UK, echinacea may be classed as a registered traditional herbal medicinal product or as a food supplement, whereas it is a dietary supplement in the USA and medicine in Germany. Therefore, countries have implemented different policies for licensing, dispensing, manufacturing, and marketing HDS. With such a lack of regulation of HDS, the quality, safety, and efficacy of HDS has become a great concern for patients, as well as healthcare organizations and authorities [20]. The ease of access to internet markets for HDS, which are commonly accompanied by commercial advertisements for diabetes treatments, make the issue more complicated, especially as the issue of diabetic patients taking HDS concurrently with their conventional medicines is well documented [21].

Table 1. Themes and codes for participants' answers

Theme	Codes included in the theme
I: **Perceived beneficial experiences**	➢ Feeling of wellbeing ➢ Help feeling. ➢ Disease and symptom control ➢ Immune system support
II: **Perceived harmful experiences**	➢ Negative experience after taking HDS

Healthcare organizations in different parts of the world are making significant progress in implementing and regulating CAM, especially HDS. For instance, there were only 65 WHO member states regulating herbal medicines in 1999, whereas there are now 119. In addition, the WHO has published guidelines to share information and experiences of member states on regulating and registering HDS products [22]. The main aim of regulating HDS products is to ensure their safety, quality, and efficacy. There is also an urgent need for improving the quality and safety of websites that provide patients, particularly diabetic patients, with information about HDS products [23].

Qualitative studies on patients' experiences and perceptions with CAM therapies are required. The study's findings and those of many other studies show that diabetic patients use CAM treatments enthusiastically and, in some cases, truly believe in their benefits despite a lack of evidence. Therefore, it is essential to understand their perceptions and appreciate their experiences to support them when choosing appropriate CAM treatments and avoid any harm as a result of their lack of knowledge or erroneous notions about such treatments. Many more pre-clinical and clinical studies are needed to examine the efficacy and safety of popular HDS.

4. CONCLUSION

Most CAM studies focus on the prevalence of CAM (particularly HDS) use in diabetic patients and then recommend further investigation on CAM safety and efficacy. However, there remains a lack of such studies contributing to ensuring CAM safety in diabetic patients by focusing on HDS as the most prevalent CAM modality used by patients and the type with the greatest potential to cause harm as a result of herbal drug interaction (HDIs). It is confirmed there were few studies discussing the potential risk of HDS on diabetic patients. In addition, most of these studies based their assessments theoretically or on speculation. Therefore, studying potential HDIs by considering the real-life practice of HDS use by diabetic patients is crucial.

CONSENT

Before deciding to take part in the study, the participants were fully informed of the study's purpose and the nature of their participation. They were also asked to sign a consent form.

ETHICAL APPROVAL

Ethical approval was obtained from the IRB committee of the College of Medicine at Imam Mohammed Ibn Saud Islamic University (IMSIU) (Ref.: 00311/2/2019).

ACKNOWLEDGEMENT

The author is thankful to Medical Services Centre, Male Clinics, Imam Mohammad Ibn Saud Islamic University (IMSIU), Riyadh, KSA.

COMPETING INTERESTS

Author has declared that no competing interests exist.

REFERENCES

1. Williamson EM, Driver S, Baxter K. Stockley's herbal medicines interactions: A guide to the interactions of herbal medicines, dietary supplements and nutraceuticals with conventional medicines. London; Chicago: Pharmaceutical Press; 2013.
2. Rankin-Box DF, Williamson EM. Complementary medicine: A guide for pharmacists. Elsevier Health Sciences; 2006.
3. National Center for Complementary and Integrative Health. Complementary, alternative or integrative health: What's in a name? 2019.
   Available:https://nccih.nih.gov/health/integrative-health
   [Accessed 8/10/2019]
4. Amaeze OU, Aderemi-Williams RI, Ayo-Vaughan MA, Ogundemuren DA, Ogunmola DS, Anyika EN. Herbal medicine use among type 2 diabetes mellitus patients in Nigeria: Understanding the magnitude and predictors of use. International Journal of Clinical Pharmacy. 2018;40(3):580-8.
5. Modak M, Dixit P, Londhe J, Ghaskadbi S, Devasagayam TP. Recent advances in Indian herbal drug research guest editor: Thomas Paul Asir Devasagayam Indian herbs and herbal drugs used for the treatment of diabetes. Journal of Clinical Biochemistry and Nutrition. 2007;40(3): 163-73.

6. Harris PE, Cooper KL, Relton C, Thomas KJ. Prevalence of complementary and alternative medicine (CAM) use by the general population: A systematic review and update. International Journal of Clinical Practice. 2012;66(10):924-39.
7. Eardley S, Bishop FL, Prescott P, Cardini F, Brinkhaus B, Santos-Rey K, Vas J, von Ammon K, Hegyi G, Dragan S, Uehleke B. A systematic literature review of complementary and alternative medicine prevalence in EU. Complementary Medicine Research. 2012;19(2):18-28.
8. Bunchorntavakul C, Reddy KR. Herbal and dietary supplement hepatotoxicity. Alimentary Pharmacology & Therapeutics. 2013;37(1):3-17.
9. Heinrich M, Barnes J, Gibbons S, Williamson EM. Fundamentals of pharmacognosy and phytotherapy; 2012.
10. Najm W, Lie D. Herbals used for diabetes, obesity and metabolic syndrome. Primary Care: Clinics in Office Practice. 2010;37(2):237-54.
11. Alrowais NA, Alyousefi NA. The prevalence extent of Complementary and Alternative Medicine (CAM) use among Saudis. Saudi Pharmaceutical Journal. 2017;25(3):306-18.
12. Medagama AB, Bandara R, Abeysekera RA, Imbulpitiya B, Pushpakumari T. Use of Complementary and Alternative Medicines (CAMs) among type 2 diabetes patients in Sri Lanka: A cross sectional survey. BMC Complementary and Alternative Medicine. 2014;14(1):1-5.
13. Sheikhrabori A, Dehghan M, Ghaedi F, Khademi GR. Complementary and alternative medicine usage and its determinant factors among diabetic patients: An Iranian case. Journal of Evidence-based Complementary & Alternative Medicine. 2017;22(3):449-54.
14. Hillson R. Herbs and diabetes. Practical Diabetes. 2019;36(5):159-60.
15. Moretti F, van Vliet L, Bensing J, Deledda G, Mazzi M, Rimondini M, Zimmermann C, Fletcher I. A standardized approach to qualitative content analysis of focus group discussions from different countries. Patient Education and Counseling. 2011;82(3):420-8.
16. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qualitative Health Research. 2005;15(9):1277-88.
17. Barnes J. Quality, efficacy and safety of complementary medicines: Fashions, facts and the future. Part I. Regulation and quality. British Journal of Clinical Pharmacology. 2003;55(3):226-33.
18. Al-Garni AM, Al-Raddadi RM, Al-Amri TA. 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. Journal of Fundamental and Applied Sciences. 2017;9:1738-48.
19. Ernst E. How the public is being misled about complementary/alternative medicine. Journal of the Royal Society of Medicine. 2008;101(11):528-30.
20. Ajazuddin SS. Legal regulations of complementary and alternative medicines in different countries. Pharmacognosy Reviews. 2012;6(12):154.
21. Williamson EM. Interactions between herbal and conventional medicines. Expert Opinion on Drug Safety. 2005;4(2):355-78.
22. World Health Organization. WHO traditional medicine strategy 2014–2023. Geneva: World Health Organization; 2015.
23. Alsanad S, Aboushanab T, Khalil M, Alkhamees OA. A descriptive review of the prevalence and usage of traditional and complementary medicine among Saudi diabetic patients. Scientifica; 2018.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/55301