Efficacy and safety concerns regarding Complementary and Alternative Medicine use among diabetes patients

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Abstract
There has been an ever increasing rise in the use of Complementary and Alternative Medicinal (CAM) practices among general populations during past few decades. Individuals with diabetes being prone to an array of related health complications, demand special attention concerning their interest towards different CAM practices. Apart from clinical practitioner and patient based awareness programmes regarding the safety and efficacy implications of CAM therapies, stringent regulations should also be imposed on these unconventional health practices so as to strike off any major adverse events. This review is an effort to bring up the issues concerning these scientifically unproven practices with a focus on populations with diabetes.

Keywords: Complementary and alternative medicine, Diabetes, Herbal medicine, Supplements.

Introduction
Diabetes considered an ancient disease, is an endocrine disorder and affects a huge number of individuals globally. World Health Organization (WHO) estimates that more than 400 million people live with diabetes and the prevalence is escalating more evidently in developing countries.¹ According to International Diabetes Federation (IDF) statistics, diabetes accounts for one death every six seconds and number of deaths caused by diabetes was 5 million, a figure much higher than those caused by HIV (1.5 million), tuberculosis (1.5 million) and malaria (0.6 million) combined.²,³ When left undiagnosed, untreated or poorly controlled, diabetes leads to severe complications predominantly arising from persistent hyperglycaemia. Other factors such as hypoglycaemia, dyslipidaemia, hypertension and obesity are important contributors to the costly complications of diabetes. The risk for vascular disease is very high in individuals with diabetes and much of the burden results from macrovascular (coronary artery disease, peripheral arterial disease, and stroke) and microvascular (nephropathy, retinopathy, neuropathy, and small vessel vasculopathy) complications.⁴

Conventional medical practices are those which deploy modern medicines that have proven scientific evidence whereas, ‘Complementary and alternative medicine’ (CAM) constitutes a range of approaches that purport to prevent or treat disease and are mostly of traditional origin. Globally observed life-expectancy was found to be 30.9 years in 1900, 46.7 in 1940, 61.13 in 1980. A dramatic improvement in life-expectancy was achieved after 1940 which can mainly be ascribed to advances in modern medicine such as drug innovations, spread and availability of medical technology, focus on lifestyle modifications etc. The WHO has estimated a worldwide life expectancy of 71.4 years for children born in 2015.⁵,⁶ Since diabetes is a disease resulting in huge economic burden, physical and mental disability, all patients should have the privilege of receiving effective therapies with least adverse effects. According to a study conducted on prevalence and pattern of complementary and alternative medicine use, individuals with diabetes are approximately 1.6 times more likely to use CAM therapies than people without diabetes.⁷ Unfortunately, those receiving alternative medications believe diabetes is a metabolic disorder whereas in reality, it is a syndrome where majority of the patients require a comprehensive treatment plan for related disorders such as dysregulation of glucose, lipid and blood pressure homeostasis. Since most of these CAM practices have been prevailing for several decades, widespread misconception also exists on the notion that these are absolutely free from side effects. Despite the fact that most of the CAM practices do not have sufficient data on their safety and effectiveness, patients still continue to follow these age old practices even in this well advanced scientific era. In the current review an effort has been made to bring up the issues concerning these scientifically unproven practices with a focus on populations with diabetes.

CAM Therapies and Their Prevalence
Complementary therapies are used together with conventional treatments, whereas alternative therapies are used in lieu of conventional medicine. National Center for Complementary and Integrative Health (NCCIH), classifies Complementary and alternative health approaches to fall into one of two subgroups, viz., natural products and mind and body practices. Natural products (widely available and often sold as dietary supplements) consist of herbs (or
botanicals), vitamins and minerals and probiotics. Mind and body practices include a variety of procedures or techniques administered or taught by a trained practitioner or teacher (e.g., yoga, chiropractic and osteopathic manipulation, meditation, massage therapy, acupuncture, relaxation techniques, tai chi, etc.). A vast majority of patients opt for CAM therapies as a complement to conventional care rather than as an alternative choice. In a US based study, total visits to complementary medical practitioners (629 million) exceeded total visits to U.S. primary care physicians (386 million). Traditional CAM practices are extremely popular in South-Asian countries, where modern conventional medicines are often inaccessible and unaffordable to majority of the individuals. Therefore despite the perception about the efficacy of modern medicines, traditional medicine continues to be exploited by these populations.

Research suggests, CAM therapy has gained popularity due to reasons such as: (1) personal recommendations by friends and co-workers, (2) desire to avoid side effects of conventional treatments (3) the failure of conventional treatments to cure a health problem, and (4) costs associated with conventional care.

Concerns with CAM Therapies

According to the 2002 National Health Interview Survey, nearly 6 million American adults turned to CAM to treat specific health conditions since they found conventional medical treatments unaffordable. Among all people who turned to unconventional remedies, in a majority (54%) of the cases, no conventional medical professional was aware of the CAM use. This is an issue of serious concern since some of these CAM products can cause serious health complications. Although "natural", and have a long history of use, most of these traditional medicines are not necessarily safe. Use of CAMs may delay the use of effective modern conventional treatments, as well as they can cause adverse effects directly. Health risks can arise from issues such as drug-herb interactions, adulteration of the products, or presence of inappropriate amounts of active ingredients in the products etc.

Unfortunately there are also instances where, even when doctors are aware of their patients using herbal remedies, they may not be trained to recognize potentially serious side effects. Cases have been reported where adulteration of herbal remedies with ingredients not disclosed on product labelling, resulting in serious health consequences to patients. A common misconception exists regarding their acceptable safety and many assume that the safety of natural products is ensured by the government. However, unlike with prescription drugs, which have to be proved for their safety and efficacy before being marketed, the Food and Drug Administration (FDA) must demonstrate that natural supplements are dangerous before taking enforcement action. A cause of major concern with developing countries in particular is the lack of proper guidelines, scientific basis and validity of a therapy, and political consensus. Only 25 of WHO’s 191 countries have a national policy on TM/CAM and only 64 countries regulate herbal medicines. With a view to assist countries in the development of policies and regulations, WHO has published a series of technical guidelines and reviewed regulations on herbal medicines in the document “Regulatory Situation of Herbal Medicines: a Worldwide Review”. Also, lower education levels of majority of the consumers suggest that they might be less likely to seek consumer information about the safety and effectiveness of CAM treatments before using them. General risks associated with the use of CAM therapies are enumerated in Table-1.

Impact of CAM Therapies on Diabetes

The most widely used therapies among people with diabetes are, in order of importance, nutritional advice and lifestyle diets, spiritual healing, herbal remedies, massage therapy, and meditation training. Of the different CAM modalities, biologically based practices (e.g. dietary supplements, herbal products and botanical products) are the most commonly used and studied for diabetes treatment which is probably due to their wider and cheaper availability, and also being inherent in the cultures and ancestral beliefs of the people.
Some studies have reported toxicity involving CAM therapies in individuals with diabetes. Instances such as renal failure with use of the dietary supplement chromium picolinate, hepatotoxicity with ingestion of sheep bile, and poor outcomes in a group of patients after abrupt stopping of insulin injections to initiate various CAM therapies, have been documented. One of the most commonly confronted drawbacks of using CAM products for diabetes is that when combined with insulin or secretagogues, the patient may experience additive hypoglycaemia. Table 2 lists some of the possible side effects observed with the use of herbs and supplements popularly used in diabetes treatment as reported by some previous reviews and studies. Other categories of CAM practice such as acupuncture, chiropractic therapy etc. are also not free of adverse effects. In individuals with diabetes, quality of life was not found to improve upon CAM use and a dose-response relationship trend was noted, whereby higher CAM use resulted in a more negative quality of life in people with Type 2 diabetes (T2DM) and/or cardiovascular disease probably attributed to the negative effects of using multiple therapies and their interactions with conventional care. During CAM use, T2DM patients also showed decreased adherence to prescribed medications.

### Prospective Use of CAM Therapies

Findings to date do not provide sufficient evidence for advocating CAM in diabetes and hence it is of utmost importance that healthcare professionals be aware of the increase in the number of patients who resort to CAM practices. Lack of proper communication between patients and healthcare professionals regarding CAM use can often result in disease mismanagement. Therefore, it is highly recommended that conventional practitioners be well informed of patient’s CAM use and understand the patient perspectives in order to take better clinical decisions. Patients with diabetes should be made alert that some of these therapies are usually ineffective or even harmful other than giving some sense of mental comfort for a short duration. In patients who persist on using alternative treatments, it is advisable to identify the effects of each of the components of these medications so that patients can be counselled regarding any contraindications to any of the constituents. They are to be adequately monitored and warned of the potential unwanted effects and physicians have to be aware of the potential interactions between the active components of the alternative medications and other prescribed medications. Strict regulations should be brought upon alternative treatments so that they are subjected to quality assessments and scientific testing no less rigorous than that required for conventional treatments in order to ensure their safety and efficacy.

### Conclusions

The use of CAM therapies among diabetes patients being prevalent, care providers are encouraged to consider their potential risks and benefits. Awareness programmes on judicial use of CAM practices might turn useful for individuals with diabetes and will encourage them to communicate openly with their health care practitioners about the pros and cons of CAM therapies, while giving due attention to their disease history and health status. Regulatory authorities must impose stringent rules to control and legalise the use of safe and proven remedies in the treatment of diabetes. In light of strictly controlled clinical trials, existing rules and regulations should be re-evaluated on different CAM practices and products which will in turn facilitate, better treatment outcomes as well as

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**Table 2: Side effects of herbs or supplements used in diabetes treatment.**

<table>
<thead>
<tr>
<th>Herb/supplement</th>
<th>Possible Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Momordica charantia (bitter melon)</td>
<td>Gastrointestinal discomfort, Hypoglycaemic coma, Favism, Haemolytic anaemia in persons with G-6PDH deficiency, Abortifacient activity.</td>
</tr>
<tr>
<td>Cinnamomum cassia (cinnamon)</td>
<td>Hypoglycaemia if combined with secretagogues, Warrants caution with the use of anticoagulants.</td>
</tr>
<tr>
<td>Gymnema sylvestre (gymnema)</td>
<td>Hypoglycaemia if combined with secretagogues.</td>
</tr>
<tr>
<td>Trigonella foenum graecum (fenugreek)</td>
<td>Gas, Bloating, Diarrhoea, Contraindicated in pregnancy; Allergic reactions, May increase anticoagulant effects of warfarin or herbs with anticoagulant activity.</td>
</tr>
<tr>
<td>Opuntia streptocantha (prickly pear cactus, nopal)</td>
<td>Diarrhoea, Nausea, Abdominal fullness; Additive effects on blood glucose and insulin with sulfonyleureas without hypoglycemia.</td>
</tr>
<tr>
<td>Panex ginseng, P. quiquefolius (ginseng)</td>
<td>May interfere with effect of anti-coagulation and anti-platelet medications, Estrogenic effect with breast tenderness, amenorrhoea, vaginal bleeding, impotence, Hypertension, Insomnia, Additive hypoglycaemia with secretagogues.</td>
</tr>
<tr>
<td>Alpha-lipoic acid</td>
<td>Allergic reactions affecting the skin, including rashes, hives, and itching. Monitor thyroid function in patients with thyroid disease.</td>
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<tr>
<td>Omega-3 fatty acids</td>
<td>Additive hypoglycaemia with diabetes medications such as Glipizide, Glyburide, Metformin, Insulin etc. Intake &gt; 3g may increase risk of bleeding, May increase LDL and cautious use is recommended in patients with very high LDL, health risks associated with certain fish as they may contain high levels of contaminants like methyl-mercury.</td>
</tr>
</tbody>
</table>
aid in considering more number of these unconventional practices to be included under conventional practice.

References
3. Hirschler B. Diabetes now kills more than HIV, tuberculosis and malaria combined. The Huffington Post, The Times of India; 2015 cited 11 June, 2016; Available from URL: http://www.huffingtonpost.com/entry/diabetes-deaths_us_5643e784e4b08cda348777bf?section=india
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