A cautionary tale on the use of complementary therapies

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ARTICLE POINTS

1 The use of complementary therapies is increasing.

2 Some complementary therapies can complement conventional diabetes management.

3 Drug interactions, contraindications and side effects are possible with some complementary therapies.

4 Education and competency are important aspects of safety.

5 Communication between complementary and conventional practitioners is essential.

KEY WORDS
- **Complementary therapy**
- **Conventional medicine**
- **Traditional Chinese medicine**

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Introduction

The use of complementary therapies is increasing. Some complementary therapies may help to stabilise, reduce or eliminate the need for diabetic medication for type 2 diabetes. Others are said to be useful in treating the symptoms of diabetic complications. However, there is a risk of adverse events with some complementary therapies, including those that arise after interaction with conventional medicines. A case study of a woman who used a Chinese herbal preparation to treat her diabetes is used to discuss some of the issues relating to the use of complementary therapies by people with diabetes.

The use of complementary therapies is increasing in all parts of the world. Most population surveys in Western countries estimate that at least 50% of the population use some form of complementary therapy (Lloyd et al, 1993; Eisenberg, 1998). Their use may be even higher in some cultural groups, e.g. use of traditional Chinese medicine (TCM) and Ayurveda in Asian communities. Complementary therapies are used by a range of people, but more often by women, of all ages, who are well educated and financially secure. Other major users are those in poor health with chronic diseases and people interested in self-care (Lloyd et al, 1993; MacLennan et al, 1996). People often begin to use complementary therapies after a traumatic life event; this could apply to some people with diabetes for whom the diagnosis is devastating.

Philosophy

The philosophy underlying most complementary therapies consists of four main elements:
- The individual is unique.
- Balance & harmony are essential to health.
- The body has the capacity to heal itself.
- Symptoms are a guide to the imbalance.

The purpose of any intervention is to restore balance and a range of approaches, addressing psychological, spiritual and physical parameters, may be required in order to achieve balance and harmony (Pizzorno and Murray, 1993). Most of this philosophy is not so different from the philosophy underpinning conventional therapies. In particular, achieving balance (good control) is central to diabetes management and there is increasing recognition of the effects of psychological parameters on blood glucose levels (Mazze et al, 1984; Bradley, 1994).

Consumer surveys show positive attitudes to complementary therapies in Western countries (Kotsirilos, 1995). However, people rarely reject conventional care, and in many cases attend both conventional and complementary practitioners, often at the same time for the same problem. In many cases they do not inform their conventional carers that they are using complementary medicines, which could lead to unwanted interactions, side effects and less than optimal outcomes.

Widespread use

The prevalence of the use of complementary therapies by people with diabetes is largely unknown. A survey of an outpatient diabetes clinic in the UK found that over 17% of patients were using, or had used in the past, some form of complementary therapy. Most of these subjects used the therapies to reduce anxiety and no major problems were reported (Leese et al, 1997).

In a Canadian study, Ryan et al (1999) found that subjects with diabetes were using garlic, echinacea, various herb mixtures, glucosamine sulphate and chromium for a variety of reasons including diabetes. They concluded that:
- The therapies were beneficial, but not as

effective as prescribed medications.

- 25% of people with diabetes take alternative therapies.
- People use alternative therapies for a number of reasons; controlling blood glucose levels may not be their prime goal.

Ryan et al's (1999) concept of 'benefit' may have been different from the expectations of the subjects in their study. Some of the reasons people with diabetes use complementary therapies are shown in *Table 1*.

Uptake by conventional medicine

Conventional health professionals are beginning to incorporate a range of complementary therapies into their practices. In 1995, it was estimated that over 3000 doctors were obtaining complementary therapy qualifications and integrating the therapies into conventional treatments, e.g. acupuncture (Kotsirilos, 1995).

A few studies report conventional health professionals using complementary therapies in the management of patients with diabetes. Massage has been shown to decrease anxiety and lead to improved blood glucose control in children, and their parents also reported reduced stress levels (Field et al, 1997). In Australia, a survey of 38 diabetes educators found that 11 recommended complementary therapies to their patients to improve blood glucose levels, decrease stress, alleviate pain and improve wellbeing (Dunning, 1998).

Research accumulating

In addition, research into complementary therapies is increasing in units attached to major hospitals and universities. Some of this research applies to diabetes, e.g. investigation into the role of antioxidants in the development, prevention, and treatment of diabetic complications is ongoing in a number of places throughout the world. Although opinion is divided about the benefits of antioxidant therapy, there is accumulating evidence that oxidation plays a role in the development of diabetic vascular disease (O'Brien and Timmins, 1999; Verdejo et al, 1999).

Some herbs have been shown to reduce blood glucose in type 2 diabetes, e.g.

- American ginseng, *Panax quinquefolius* (Sotaneimi et al, 1995; Vuksan et al, 2000).
- Gymnema (Baskaran et al, 1990).
- Fenugreek in both type 1 and type 2 (Sharma et al, 1996).

A number of other herbs such as bitter melon, bilberry leaf, and goat's rue (from which metformin is derived) are frequently used. Likewise, the use of chromium supplements has increased and there is some evidence that it improves blood glucose control in type 2 diabetes (Anderson, 1997).

Complementary therapies are defined as health systems, modalities, practices and accompanying beliefs that lie outside the politically dominant health system of a culture in a given historical period. The boundaries within, and between, therapies are not always fixed and clear (Cochrane Collaboration, 2000). In this context, TCM is regarded as a complementary therapy in Australia but in Chinese cultures it is often regarded as an alternative medical system. TCM is widely used in China, Hong Kong, Singapore and Malaysia, not only by Chinese communities, but others as well. The use of TCM is increasing in Australia and other Western cultures. The increased usage is partly cultural, following increased migration of people from Chinese backgrounds, and partly associated with the general trend towards use of complementary therapies. A range of other complementary therapies are in common use in many countries (*Table 2*).

Dangers of contamination

Although herbs themselves may be beneficial, herbal products are often adulterated with other, often potentially dangerous substances. Animal products, minerals, prescription drugs, heavy metals, digitalis, steroids, active oestrogenic substances, ephedrine, methyltestosterone and phenacetin have all been identified in herbal products of

Table 1. Reasons for which people with diabetes use complementary therapies.

- To control blood glucose
- To manage symptoms of diabetes and its complications
- To relieve stress, anxiety and depression
- To improve quality of life
- As part of preventive care, e.g. foot care
- As part of their normal lifestyle
- It is a cultural or philosophical preference
- For reasons unrelated to diabetes, e.g. arthritis.

Table 2. Commonly used complementary therapies worldwide.

- Acupuncture
- Aromatherapy
- Ayurveda
- Chiropractice
- Herbal medicine
- Kinesiology
- Massage (many traditions & techniques)
- Meditation
- Music
- Naturopathy
- Nutritional therapies/ supplements
- Pet therapy
- Psychotherapeutic approaches
- Reflexology
- Reiki
- Therapeutic touch
- Traditional Chinese medicine

Chinese or Indian origin (Ko, 1998, Beigel and Schoenfeld, 1998). Some of these adulterants have been associated with adverse events in people with diabetes, e.g. lead poisoning (Beigel et al, 1998), hospital admissions of patients using herbal preparations for blood glucose control (Gill et al, 1994).

Dangers of mistreatment

Other practices have also led to morbidity in diabetic patients, e.g. burns and trauma to neuropathic legs from cupping and moxibustion (Ewins et al, 1993) and ketoacidosis from stopping insulin in type 1 diabetes (Gill et al, 1994). The Case Study (below) illustrates some of the issues associated with the use of a Chinese herbal preparation to treat diabetes.

Traditional Chinese medicine

TCM is a complex system of health practices that has been used for over 3000 years. It embraces many theories, methods and approaches (*Table 3*). TCM practitioners view human physiology, diagnosis and treatment differently from conventional medical practitioners. The concept of *qi* or vital energy, and *yin/yang*, the interaction of opposites such as male and female, light and dark, forms the basis of TCM. Diagnosis often focuses on detecting patterns and imbalances in an individual to develop an individual care plan. TCM terminology is confusing and is partly responsible for some of the misunderstanding between complementary and conventional practitioners. This is clearly demonstrated by the information on the medication used by

Case Study

LL, a Chinese woman of 35 years, was referred to the outpatient clinic of a university teaching hospital by her general practitioner for assessment and management of newly diagnosed type 2 diabetes.

On examination she had no evidence of any complications. She was 1.62m tall and weighed 75kg Her blood pressure was 130/80mmHg with no postural drop, and her random blood glucose was 17.5 mmol/l. She was commenced on glibenclamide mg BD and given routine diabetes education. She was very distressed by the diagnosis and did not return for follow-up care despite being sent several appointments. Nine months later she returned to the outpatient clinic with polyuria, polydipsia and tiredness. Her blood glucose at the time was 20.7 mmol/l and there was no ketonaemia.

During discussion with the diabetes educator, it emerged that she had consulted a TCM practitioner, after being given the initial diagnosis, who prescribed a herbal preparation known as Yuan Heng Yi Tai Chong Ji. The main ingredients were listed (in English) on the package insert as 'pumpkin powder, Salviae miltiorrhzae, lycium Chinese, etc, root of kudzu vine, Astragalus membranaceus, etc'. A diet and exercise regimen, consistent with conventional recommendations, was also prescribed.

The actions of Yuan Heng Yi Tai Chong Ji, translated into English, were listed on the package insert as, 'strengthening the middle-warmer and benefiting vital energy, nourishing YIN and promoting the production of body fluid'. Several indications for use were listed on the package including 'diabetes due to deficiency of vital energy, and yin, with symptoms such as lassitude, red tongue and deficiency of body fluid, enlarged tongue in red colour thin coating of the tongue or with peeling at places: pulse-deep or rapid'. It was recommended for both type 1 and type 2 diabetes and claimed no side effects. It alluded to, but did not reference, a clinical study that demonstrated 91% effectiveness.

The preparation was a powder packaged in individual 8g sachets. The recommended dose was one sachet three times per day taken with lukewarm water. The herbal preparation represented a considerable expense for the patient, but she continued to take it for six months, and reported home blood glucose monitoring levels in the range 6–10 mmol/l while on the preparation. HbA_{1c} estimation was not performed at this time as she did not attend conventional medical care while taking the herbs.

The patient had stopped the preparation when the cost became prohibitive and her blood glucose increased to an average of 18 mmol/l. At outpatient clinic, LL was recommenced on gliblencamide 10 mg BD.

Six months later, LL was changed to insulin, Mixtard 30/70, 10 units before bed because her control did not improve. She had one remaining sachet of the herbal preparation that she gave to the diabetes educator to be analysed. Analysis was carried out at the Department of Pharmacology, University of Malaya, using high pressure liquid chromatography (HPLC), which revealed the presence of glibenclamide.

the woman in this case study. Expressions such as 'middle-warmer' and 'deficiency of YIN', are outside the experience of most conventional practitioners.

Potential dangers

Despite some positive benefits of TCM for people with diabetes, the case study raises several concerns about its use, e.g.

- Product labelling
- Misleading/omitted information
- Contamination by another substance.

These factors have implications for the safety and efficacy of the product, and the label may not conform to codes of good manufacturing practice. In addition, there is the possibility that inappropriate use of the preparation would lead to hypoglycaemia, especially in someone without diabetes.

The preparation was said to be indicated for type 1 and type 2 diabetes. Clearly, the preparation would not be suitable for type 1 diabetes, and if it was used, could lead to ketoacidosis and death, particularly as the information suggested that insulin could eventually be stopped. Likewise, the indications for the preparation do not necessarily only apply to diabetes, and hypoglycaemia would be a major risk if it were to be prescribed for people who do not have diabetes.

Adulteration of herbal products not only has the potential for adverse events, but in many cases not all of the ingredients are listed, as was the case here, where glibenclamide was not on the list. In addition, taking adulterated herbal preparations can delay diagnosis and appropriate treatment (Beigel et al, 1998).

Safety issues

Safety issues encompass factors besides the quality and safety of herbs, and other preparations and techniques used in complementary therapies. Safety includes:

- Appropriate patient assessment and diagnosis.
- Selection of an appropriate treatment that is used correctly.

In many cases, people self-diagnose and self-treat, often inappropriately, and without all the relevant information. Such practices can result in delay in seeking appropriate care, uncoordinated care and less than optimal outcomes.

Table 3. Outline of the main modalities in traditional Chinese medicine.

Modality	Brief description
Herbs	Typical herbal prescriptions contain many herbs and sometimes animal and mineral products as well. The herbs are prepared for administration in many ways and taken internally (e.g. as infusions) as well as externally (e.g. compresses).
Acupuncture	Insertion of thin needles at specific points that relate to the energy channels of the body (meridians).
Acupressure	Stimulation of pressure points using direct pressure with the fingers or hands rather than needles.
Massage	The systematic manipulation of muscles and soft tissues of the body to relieve tension and pain, assist in the removal of fluid and toxins and aid wellbeing.
Diet	Food is regarded as a medicine and also has yin/yang and energetic properties. Foods are used for their heating, cooling, moistening or drying effects for specific conditions.
Quigong	There are many forms of quigong, principally exercise, breathing techniques and meditation
Moxibustion	Burning a mound of moxa, a plant (*Artemesia vulgaris*), on points near the meridians either directly on the skin or on acupuncture needles. The heat penetrates and stimulates or inhibits to restore balance.

Other issues that affect safety include the knowledge and competence of the therapist, monitoring and evaluation of the treatment and consultation and referral when indicated.

Even safe therapies can have adverse outcomes when delivered by untrained people, and this includes complementary therapies delivered by inadequately trained conventional practitioners.

Non-conventional medicines

Over 700 plants have been attributed with hypoglycaemic properties (Ivorra et al, 1989; Pizzorno and Murray, 1993; Day, 1995). The hypoglycaemic effect is said to be a result of a number of chemical constituents contained in plants, e.g. glycans, glycosides, saccharins, flavinoids, steroids and terpenoids. Some plants also contain insulin-like peptides and polypeptides. These substances are extracted from seeds, leaves, roots, tubers and rhizomes (Ivorra et al, 1989).

PAGE POINTS

1 Ensuring safety of complementary therapy products covers many issues.

2 Plants with hypoglycaemic properties are not generally recommended for people with type 1 diabetes.

3 Before using a complementary therapy, patients should seek information on its action and interaction with conventional therapies.

4 Communication between the patient and conventional and complementary health professionals is essential.

5 Conventional practitioners must consider the possibility that their patients are using complementary therapies.

Plants with hypoglycaemic properties are not generally recommended for people with type 1 diabetes. Hypoglycaemic effects are said to be the result of stimulation of the production and release of insulin — decreased insulin resistance and delayed uptake of food from the gut leading to an improved glucose profile (Pizzorno and Murray, 1993).

More knowledge needed

Although some of the constituents in the preparation taken by LL may have had hypoglycaemic effects, the presence of glibenclamide was probably a major factor in her improved blood glucose control. However, when she stopped the herbal medicine and was recommenced on glibenclamide, her blood glucose was not well controlled and she eventually needed insulin. This raises the question as to whether she has slow-onset type 1 diabetes rather than type 2 diabetes.

Synergism and interactions

Alternatively, other constituents in the preparation may have had hypoglycaemic effects, or the combination of ingredients may have played a part. Support for a synergistic effect between glibenclamide and Chinese herbs traditionally used for the treatment of type 2 diabetes is provided by a multicentre, randomised controlled trial (Vray and Attali, 1995). Little is known of the potential actions and/or interactions of the wide array of substances in the preparation used by LL and there is a lack of objective clinical evidence to support many of the claims made by the manufacturers of this, and other, herbal products.

Communication is vital

The case study highlights some of the problems that can occur when patients do not inform conventional heath professionals that they are using complementary therapies. In LL's case, there were no adverse interactions with any other medication, food or other complementary therapy; however, the presence of glibenclamide in the preparation heightened the risk of serious hypoglycaemia if oral hypoglycaemic agents or insulin had been taken concurrently. Such actual and potential problems often occur because neither the complementary practitioner, nor the conventional practitioner is aware that the patient is combining both therapies.

Valuable role if used carefully

Despite the negative issues raised by this case, complementary therapies can have a role in diabetes care, e.g. massage has both physical and psychological benefits and contributes to improved blood glucose profiles (Field et al, 1997).

However, all available information relating to the therapy, its use in combination with conventional treatment and a thorough assessment must be carried out, and an accurate diagnosis made before complementary therapies are used. Communication between the patient and conventional and complementary health professionals is essential.

TCM and other complementary therapies are so widely used that conventional practitioners must consider the possibility that their patients could be using them, and ask about their use. Questions about the use of complementary therapies should be part of the routine health history. Importantly, a non-judgmental attitude is vital to enable people to feel comfortable discussing complementary therapies with their conventional carers.

Educating TCM practitioners about diabetes can have positive benefits for patients and lead to improved healthcare services and patient outcomes. Educating conventional practitioners about complementary therapies is equally important for the same reasons. In fact, a growing number of universities are incorporating complementary therapy units into their undergraduate nursing and medical degrees — studies in complementary therapies up to doctoral level are available.

Patients are entitled to honest, unbiased advice, based on knowledge, and where possible, appropriate evidence. Use of any non-conventional products should be within the framework of safe medication usage, in the same way conventional drugs are used. Patients should be counselled to obtain as much information as possible about any therapy before they use it. Some specific considerations are shown in *Figure 1*.

Conclusion

TCM and other complementary therapies can have a role in the management of diabetes provided they are used following a thorough assessment, an accurate diagnosis and based on well designed research evidence, where it exists. Both complementary and conventional practitioners should be aware of the treatment modalities their patients are using. Education about complementary therapies and diabetes of both complementary and conventional practitioners is important. ■

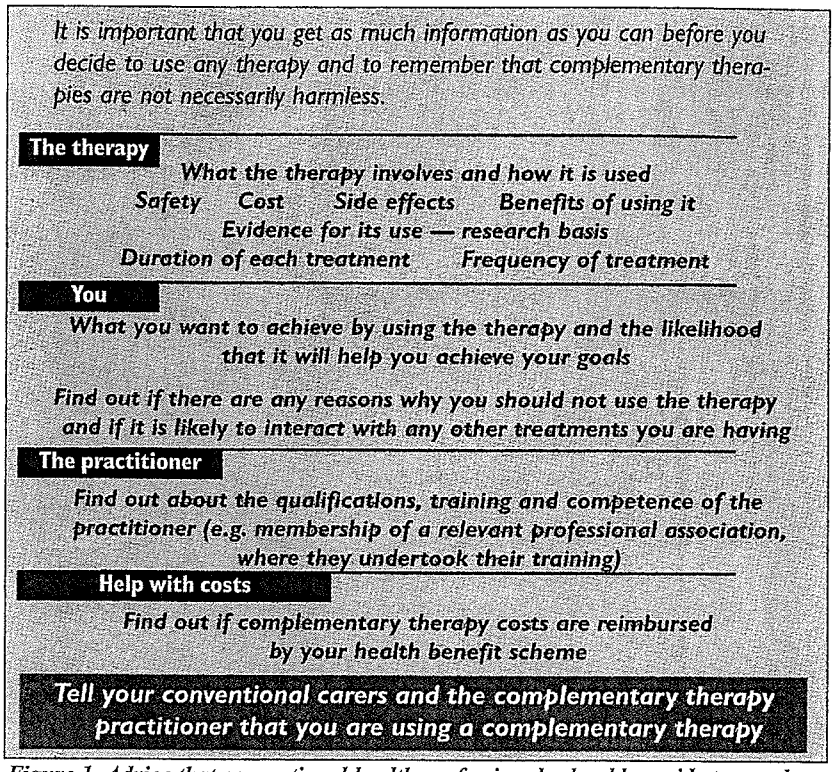

Figure 1. Advice that conventional health professionals should provide to people with diabetes considering using complementary therapies.

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