

Top ten natural preparations for the treatment of diabetic foot disorders

Hasan Ali Alzahrani, Balkees Abed Bakhotmah

Abstract

Background: In Saudi Arabia, the self-care practices of patients with diabetes when they develop diabetic foot disorders (DFDs) such as open wounds, ulcers, and skin cracks are unknown. Local culture and beliefs usually play a part. **Aims:** To identify the top ten natural preparations which are commonly used by a cohort of Saudi patients with diabetes in Jeddah, Western Saudi Arabia when exposed to DFDs. **Methods:** A cross-sectional descriptive study of a representative cohort of patients with diabetes was designed. A pre-designed questionnaire was carried out by a group of trained nutrition students to the patients living in their neighbourhoods. **Results:** The most commonly used natural preparations were honey (56.6%), followed by *Commiphora molmol* (myrrh) (37.4%), and *Nigella sativa* (black seed) (35.1%). The least used was *Lawsonia inermis* (henna) (12.1%). The top ten combinations of natural preparations used topically to treat DFDs were also identified. **Conclusions:** The use of natural preparations to topically treat DFDs is common among Saudi patients with diabetes. Honey was the most commonly used preparation on its own, or in combination with others. **Conflict of interest:** None.

KEY WORDS

Diabetic foot disorders (DFDs)
Natural preparations
Complementary and
alternative medicine (CAM)
Self-care practices

At least one in five Saudis, i.e. approximately four million are affected by diabetes (Elhadad et al, 2007). Al-Nozha et al (2004) quoted an overall prevalence rate of diabetes of 23.7% in Saudi Arabia. Foot disorders are among the most feared complications of diabetes (Al Zahrani et al, 1992). Over the last 20 years, the authors' group have reported that ulcers are the most common diabetic foot disorder (DFD) (Al Zahrani et

al, 1992; Badri et al, in press). If not treated or managed appropriately, the ultimate endpoint of diabetic foot ulcers is amputation (Al-Tawfiq and Johndrow, 2009). Amputation is usually associated with significant morbidity (Robbins et al, 2008) and mortality (Tentoulouris et al, 2007; Zgonis et al, 2008; Schofield et al, 2006), as well as immense social, psychological and financial consequences (Boutoille et al, 2008; Khanolkar et al, 2008).

Self-medication with oral natural preparations and herbs is common both in developed and developing countries for many illnesses, as part of complementary and alternative medicine (CAM) (Egede et al, 2002; Garrow and Egede, 2006; Modak et al, 2007). In the USA, for example, a dramatic increase in overall use of CAM in adults with diabetes has been noticed (2002 National Health Interview Survey), with people with diabetes being more likely to use herbs, yoga, or vitamins compared to persons without diabetes (Garrow and Egede, 2006).

Natural products and herbal formulations are preferred in developing countries because they have less side-effects and are cheaper than conventional medicines (Modak et

al, 2007). However, their preference depends on other factors too, including:

- ▶▶ Cultural background
- ▶▶ Education
- ▶▶ Socioeconomic factors
- ▶▶ Nature of health problem and the availability of local remedies.

In Western Saudi Arabia, local habits and health practices are influenced by Islamic culture and literature, which value the use of CAM as part of spiritual life. Al-Rowias et al (2010) recruited 1408 people for their study and found that natural preparations were prescribed by traditional healers to 43.2% of their sample. The common medical problems for seeking traditional healers' help were abdominal pain, flatulence, low back pain, sadness, depression, and headache. The common reasons for visiting traditional healers were belief of success of CAM (51%), preference of natural materials (29%), and non-response to medical treatment (25%).

Topical treatment of diabetic foot wounds and ulcers is not uncommon (Frykberg et al, 2006). Honey is perhaps one of the most widely used natural products (Jull et al, 2008). Evidence from animal studies and trials has suggested that honey may accelerate

Professor Hasan Ali Alzahrani is Chairman of 'Mohammad Hussein Al-Amoudi Chair for Diabetic Foot Research', Professor of Surgery, Consultant Vascular Surgeon, Department of Surgery, KAU Medical College, King Abdulaziz University, Jeddah, Saudi Arabia; Dr Balkees Abed Bakhotmah is Assistant Professor, Department of Nutrition and Food Sciences, KAU Girls Education Colleges, King Abdulaziz University, Jeddah, Saudi Arabia

wound healing (Jull et al, 2008). In Saudi Arabia, some herbs, natural preparations and CAM products are occasionally combined with honey, or used separately by people with diabetes. Similar to other patients in developed countries (Sprague et al, 2007), the authors' patients use natural preparations and CAM products to treat their chronic wounds, with or without clinical consultation, as they feel that it is not an important issue to discuss with healthcare professionals.

There is a lack of scientific evidence about the current habits, practices and beliefs of patients with diabetes in Saudi Arabia when they suffer from foot disorders such as open wounds, ulcers, infected in-growing toenails, etc. It has been found that local culture and beliefs usually influence self-care (Elhadad et al, 2007; Rai and Kishore, 2009).

In this study, the authors aimed to identify those patients with DFDs who preferred conventional treatment, versus those who favoured traditional therapies, i.e. alternative or complementary treatment, or a combination of both types of intervention. The top ten natural preparations commonly used to treat DFDs were also identified. Such information may form a database for further research.

Design/methods

A cross-sectional descriptive study was performed on a cohort of 1634 Saudi patients with diabetes living in Jeddah, Western Saudi Arabia. The sample was collected over a two-month period (March and April, 2008). Data was collected by a group of 40 trained final year undergraduate nutrition students as part of their research module. The students lived in different areas of Jeddah. This comprehensive distribution of the studied clusters enhanced the representation of different socio-economic groups in Jeddah, which has a population of more than 1.5 million (Central Department of Statistics and Information [CDSI], 2004). The principal investigator trained and supervised the interviewers.

Interviewers recruited any known patient with diabetes living in their

neighbourhood, including relatives, neighbours and friends. Non-Saudis or those who declined to participate were excluded from the study. Each interviewer was requested to enrol approximately 40 patients (range 35–45 patients from each district), to ensure a fair representation across the city. Verbal, informed consent was obtained after the study had been explained in the patient's native language. The study was approved by the ethical committee of King Abdulaziz University Hospital (Ref no 294).

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A pre-designed questionnaire was compiled by the authors based on their local experience to identify the local practices of patients with diabetes when dealing with any foot disorder/complication. For the study's purpose, DFDs were defined as one or more of the following presentations: open wounds, chronic ulcers, infected in-growing toenails and skin cracks. The questionnaire was piloted on a group of patients with diabetes before the students interviewed patients face-to-face in their respective localities and filled out the questionnaire.

The questionnaire consisted of seven sections:

- ▶▶ Demographic data, including age, sex, smoking and other comorbid conditions
- ▶▶ Patients' history of diabetes, including duration and treatment
- ▶▶ Diabetic complications, including history of foot complications and frequency. An indirect question to assess general patient knowledge about the relationship between

DFDs and a lack of commitment to dietary restrictions was also included in this section

- ▶▶ Type of treatment used by the patient, i.e. conventional versus traditional, natural therapies
- ▶▶ The traditional, natural products used. Six products were included based on the authors' previous experience of the most commonly used local remedies, namely: honey, myrrh (*Commiphora molmol*), black seeds (*Nigella sativa*), saber (*Cactaceae*), helba (*Fenugreek*), henna (*Lawsonia inermis*), with the opportunity for others to be added by the patients
- ▶▶ The combination of several products
- ▶▶ The source of information that convinced the patient to use the traditional preparation, including doctors, traditional healers, relatives/friends, magazines and internet sites.

Data entry and analysis

Data entry and statistical analyses were done using SPSS 16.0 statistical software package. Quality control was undertaken at the stages of coding and data entry. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and mean and standard deviations for quantitative variables. Quantitative continuous data were compared using Student t-test in case of comparisons between two groups. When normal distribution of the data could not be assumed, the non-parametric Kruskal-Wallis or Mann-Whitney tests were used instead of Student t-test. Qualitative variables were compared using chi-square test. Whenever the expected values in one or more of the cells in a 2x2 table was less than 5, Fisher exact test was used instead. Pearson correlation analysis was used for assessment of the inter-relationships among quantitative variables. Statistical significance was considered at p-value <0.05.

Results

A total of 1634 known Saudis with diabetes were interviewed. There was slight preponderance of males (53.1%) over females in the study group. The mean age was 49 + 17 years, and more

than half of the study group (54.6%) were in the age group of 30–<60 years.

It was observed that there was a consistently significant increase in the frequency of complications in the older age groups, ranging between 54.8% among patients aged <30 years and 87.6% among elderly patients aged 60 years and more ($p<0.05$). There was also a steady increase in the frequency of diabetic complications for those with a longer duration of diabetes; ranging between 54.2% among patients who had had diabetes for less than five years, and 86.5% in patients who had had diabetes for more than 10 years. This increase in the frequency of complications with longstanding diabetes is statistically significant ($p<0.05$). Similarly, it was noted that diabetic complications affected the majority of patients who indicated that they were unable to control their diabetes (87.7%), in addition to those who rated their control of diabetes as poor (92.5%), compared to less than half (47.8%) of those who rated control as excellent ($p<0.05$).

More than two-thirds (71.2%) of the patients said that they had suffered a DFD, as defined above, one or more times in the previous year. Half of the studied group reported that they had suffered twice from DFDs in the past year. Almost 21.1% of the study group said that they had suffered from foot ulcers more than five times in the last year.

Out of the 1006 patients who had DFDs, 353 said that they had not used any treatment compared to 653 who reported trying some sort of topical therapy. Of these, 307 patients (47.1%) had used conventional medicine alone, 142 (21.7%) mixed more than one CAM product to form a new natural preparation as an alternative topical treatment, and 204 (31.2%) used both types of treatment to complement each other (Figure 1).

The most commonly used topical natural product for treating DFDs in the authors' study was honey. More than half of the patients with diabetes (56.6%) who had a history of foot ulcers/

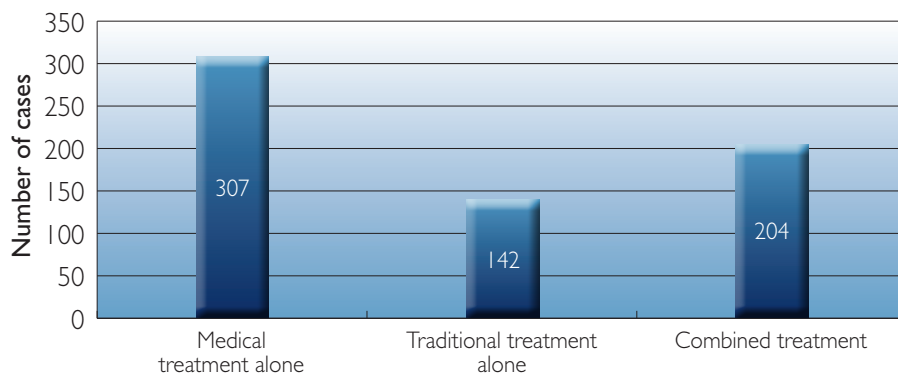


Figure 1. Types of treatment used in dealing with diabetic foot disorders as reported by 653 diabetics.

disorders indicated that they had used honey either alone or in combination with another topical remedy. It was also seen that almost one-third (37.4%) used myrrh (*Commiphora molmol*), and 35.1% used black seed (*Nigella sativa*). Fenugreek (*Helba*) was less used (12.5%), with henna (*Lawsonia inermis*) being used by 12.1% of the sample (Figure 2).

The top ten common combinations of natural preparations used for treating DFDs typically were also identified (Figure 3). The commonest combination was honey and black seeds (19.1%), followed by honey and myrrh (12.1%). The least was the black seeds and sabr (*Cactaceae*) (2.3%). All of these natural preparations or CAM products are available locally and are sold without regulations.

The patients' sources of information about traditional medicine and natural remedies were also identified. Friends and relatives, particularly those with diabetes were the commonest proxy for providing information about natural

preparations (70.8%), followed by traditional healers (38.4%). Furthermore, only one-quarter of the patients with diabetes interviewed who used natural preparations were doing so in accordance with advice from their doctor (24.9%) (Figure 4).

Finally, patient knowledge and awareness was considered reasonable by the authors when assessed indirectly by a question about the relationship between an unhealthy diet and the development of foot disorders, as 75.8% of the patients who had developed diabetic foot ulcers knew that there was a direct relationship.

Discussion

Over 80% of the populations in developing countries depend on traditional healing modalities, including herbal remedies, for health maintenance and therapeutic management of disease (World Health Organization [WHO], 2002; Modak et al, 2007; Rai and Kishore, 2009; Al-Rowais et al, 2010). As in other developing regions, CAM and herbal therapies are used in Saudi Arabia to

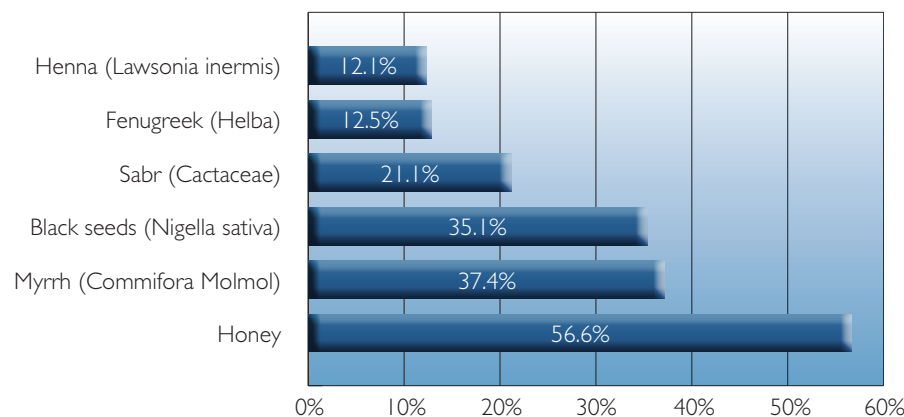


Figure 2. Natural preparations used for treating diabetic foot disorders.

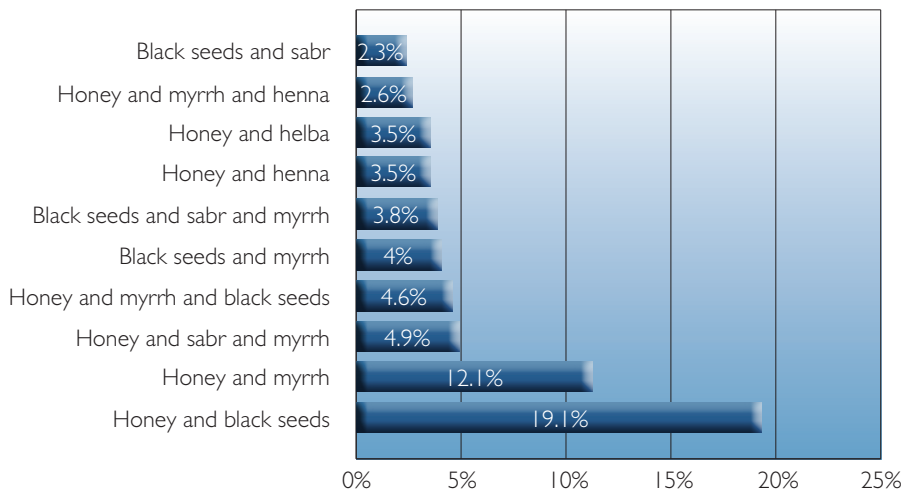


Figure 3. The top ten combinations of natural preparations used for treating DFDs by the studied cohort of Saudi patients with diabetes.

deal with diabetes and its complications (Al-Rowais 2002; Egede et al, 2002; Garrow and Egede, 2006; Modak et al, 2007; Jull et al, 2008; Al-Rowais et al, 2010). Al-Rowais et al (2010) studied the different types of CAM used in Riyadh, Central Saudi Arabia and found that herbal preparations were the most popular compared to other modalities of CAM, such as cupping and cautery. In another study in Riyadh (Al-Rowais, 2002), 17.4% of the 296 patients with diabetes studied reported using some form of herbal remedy. The commonest herbs used were myrrh, black seed, helteet, fenugreek and aloes. However, these findings were based on oral use, and did not address the use of topical preparations to treat DFDs.

In the authors' sample, DVDs (61.6%) were the second most common complication of diabetes after eye problems (78.7%). Kidney complications (35.5%) were the least common disorder experienced by this

patient cohort. The high recurrence rate and chronicity of DVDs may explain the preferential use of topical CAM products by a significant proportion of the sample, with half of the group using some CAM topical treatment alone, or in combination with a conventional therapy.

The eventual outcome of diabetic foot ulceration may be loss of the whole extremity involved (Robbins et al, 2008; Al-Tawfiq and Johndrow, 2009; Badri et al, in press). This fear will influence patients with diabetes to try all types of conventional and CAM treatments to avoid the tragedy of amputation. Although DFDs are manifestations of a systemic metabolic disorder, most patients and sometimes healthcare professionals tend to deal with them as a local problem, focusing on using topical agents which may prevent infection or promote healing, such as honey (Abdelatif et al, 2008; Jull et al, 2008).

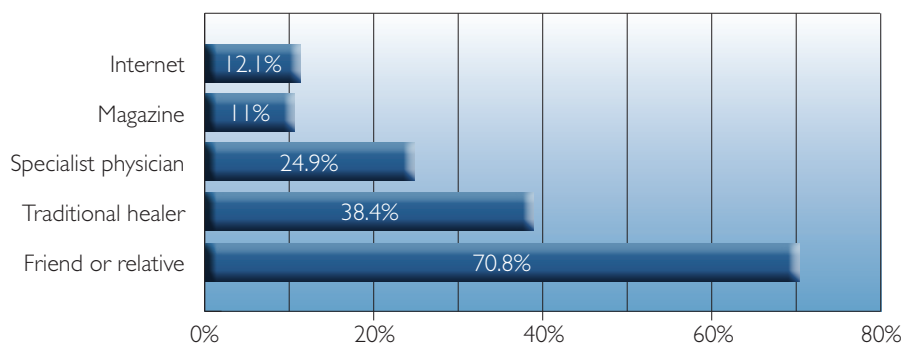


Figure 4. Sources of information about the natural preparations used in treating DFDs.

In the authors' opinion, there is little published evidence on the use of natural preparations and CAM products for the topical care of DFDs. Information is needed to further research for local complications of diabetes. Thus, the authors explored the significance of the problem, identifying the natural preparations preferred by the local community. The same patterns are expected in nearby countries with similar cultural backgrounds, including Islamic, Arab, Asian, African and Middle Eastern countries.

In this study, the authors noticed that patients with diabetes used different types of natural products, e.g. honey, myrrh (*Commiphora molmol*); herbal seeds, e.g. black seeds (*Nigella sativa*); and medicinal plants, e.g. saber (*Cactaceae*) and helba (*Fenugreek*). Thus, it may be more accurate to label these under the broad term of CAM, particularly when more than one entity is mixed with another.

Honey headed the list, as more than half of the patients with diabetes in this study (56.6%) who had a history of foot ulcers/disorders indicated that they had used honey either alone or in combination with other topical remedies. This came as no surprise as it is recognised that patients in this part of the world have used honey on a daily basis for local care of wounds, not only recently, but historically (Majno, 1975; Abdelatif et al, 2008; Jull et al, 2008), irrespective of the insufficient published clinical evidence to support its use.

Jull et al (2008) systematically reviewed the use of honey for the topical treatment of various wounds, including diabetes-related wounds, and recommended it for the treatment of venous leg ulcers and acute wounds. However, they concluded that there was insufficient evidence to guide clinical practice for other wound types, including those that occurred as a result of diabetes. A Malaysian comparative study between honey and povidone iodine as a dressing solution for Wagner type II diabetic foot ulcers showed insignificant difference in ulcer healing in both study groups (Shukrimi et al,

2008). However, they looked from a different angle, comparing honey to conventional antiseptics to prove that it was comparable and not superior. They concluded that honey dressings were a safe alternative dressing for diabetic foot ulcers, as they improve wound healing, prevent superadded infection and are readily available at an affordable cost in most developing countries (Mahabir and Gulliford, 1997; Molan, 2004; Shukrimi et al, 2008; Eddy et al, 2008; Jull et al, 2008).

The absence of randomised controlled trials (RCTs) does not necessarily mean that honey should not be used, as there are many studies advocating its use, particularly those done on Manuka honey (Molan, 2004). Manuka honey was approved as a wound dressing by the US Food and Drug Administration (FDA) in 2007 (Eddy et al, 2008). An RCT on the use of honey in treating diabetic foot ulceration is ongoing by Eddy et al in the US (Eddy et al, 2008).

Given honey's potential for improved outcomes, cost-effectiveness and helping to decrease antibiotic use and resistance, the authors support the findings of others that topical honey is a suitable therapy for patients with refractory diabetic foot ulcers (Molan, 2004; Abdelatif et al, 2008; Eddy et al, 2008; Shukrimi et al, 2008).

The second natural product used by the patients in this study was myrrh (*Commiphora molmol*). While the collection of the gum resins was initiated in Arabia, myrrh is one species of the resin-bearing plants that grows across the Red Sea in the area that is now Somalia and Ethiopia. Myrrh possesses significant antiseptic, anaesthetic and anti-tumour properties. These properties are directly attributable to terpenoids (especially furanoses-quitperenes), the active compounds present in myrrh essential oil. Recently, studies have focused on applying clinical trial methodologies to validate its use as an antineoplastic, an antiparasitic agent, and as an adjunct in healing wounds (Nomicos, 2007; Tonkal and Morsy, 2008). It has been prescribed for treating

skin infections and periodontal abscesses (Tonkal and Morsy, 2008). It also has some antibacterial and antifungal activity against standard pathogenic strains of *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans* (Dolara et al, 2000).

The third preferred natural product used was black seed (*Nigella sativa*). Black seed has been used for medicinal purposes for centuries, both as a herb and pressed into oil, in Asia, the Middle East and Africa. It has been traditionally used for a variety of conditions and treatments related to respiratory health, stomach and intestinal health, kidney and

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liver function, circulatory and immune system support. It has also been used as an analgesic, anti-inflammatory, anti-allergic, antioxidant, anticancer and antiviral therapy, as well as for general well-being. The seeds contain both fixed and essential oils, proteins, alkaloids and saponin (Ali and Blunden, 2003). The seeds/oil have anti-inflammatory, analgesic, antipyretic, antimicrobial and anti-neoplastic activity (Salem, 2005), and are characterised by a very low degree of toxicity. However, two cases of contact dermatitis have been reported following topical use (Slem, 2005). Different crude extracts of black seed were tested for antimicrobial effectiveness against different bacterial isolates by Morsi (2000), who found that Gram-negative isolates were affected more than Gram-positive ones. Most of the authors' patients used the crude extracts.

Although the targeted sample in this study was not randomised, in the authors' opinion it was a representative

convenient sample as the interviewers covered a wide geographic area across Jeddah. The authors were concerned about the respondents giving reliable answers to the questionnaire's items, particularly those who were uneducated or from lower socioeconomic groups. To overcome this weakness, a question about the relationship between DFDs and poor control of diabetes and/or longer duration of diabetes was included to assess the patients' knowledge and reliability in giving serious answers to the questions.

The results of this study indicate that the high prevalence of natural preparations used in Jeddah, Saudi Arabia may be attributable to the patients' underlying beliefs that they are efficacious and, in some cases, more efficacious than conventional medicines. If we accept that this practice has been around for some time, there is an urgent need for regulations on CAM and for public awareness campaigns regarding bad practice. The authors recommend that healthcare professionals gain a greater understanding of natural preparations, especially with regard to their potential interactions with conventional medicines so that they can better communicate with their patients and include them in treatment regimens.

Well-designed, controlled clinical trials to establish the safety profile and efficacy of the commonest natural preparations used by patients with diabetes should be conducted. Such evidence-based studies would provide research to help healthcare professionals make informed decisions when outlining treatment and management options for patients with DFDs and, more importantly, help to guide patients on the use of natural preparations. **WUK**

Acknowledgements

We would like to thank all students who participated in data collection. Special thanks to Dr Adel Ibrahim (for statistical advice). Finally, we are grateful to 'Mohammad Hussein Al-Amoudi Chair for Diabetic Foot Research' for funding this research, without which the study would not have been possible.

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Key points

- ▶ In developing countries, natural products and herbal formulations are preferred because they have less side-effects and are more cost-effective than conventional medicine.
- ▶ Patients' preference for natural preparations depends on many factors including cultural background, education, socioeconomic factors, and nature of health problem and availability of the remedies in the local market.
- ▶ The most commonly used natural preparations in Jeddah were honey (56.6%) followed by myrrh (*Commiphora molmol*) in 37.4% and black seed (*Nigella Sativa*) in 35.1%.
- ▶ Healthcare professionals should gain a greater understanding of natural preparations in order to improve communication with patients regarding their potential interactions with conventional medicine.
- ▶ Health education campaigns on wound care for patients with diabetes should raise awareness of best practice.