

A SURVEY OF HERBAL REMEDY USERS

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Abstract

Aims: To determine whether adverse drug reactions (ADRs) to herbal remedies would be reported differently than similar ADRs to conventional over-the-counter (OTC) medicines by herbal-remedy users.

Methods: Face-to-face interviews (using a structured questionnaire) with 515 users of herbal remedies were conducted in six pharmacy stores and six healthfood stores in the UK. The questionnaire focused on the likely course of action taken by herbal-remedy users after experiencing an ADR associated with i) a conventional OTC medicine and ii) a herbal remedy.

Results: Following a “serious” suspected ADR, 156 respondents (30.3%) would consult their GP irrespective of whether the ADR was associated with the use of a herbal remedy or a conventional OTC medicine, whereas 221 respondents (42.9%) would not consult their GP for a serious ADR associated with either type of preparation. 134 respondents (26.0%) would consult their GP for a serious ADR to a conventional OTC medicine, but not for a similar ADR to a herbal remedy, whereas 4 respondents (0.8%) would consult their GP for a serious ADR to a herbal remedy, but not for a similar ADR to a conventional OTC medicine. Similar differences were found in likely behaviour with regard to reporting “minor” suspected ADRs.

Conclusions: Consumers of herbal remedies would act differently with regard to reporting an ADR (serious or minor) to their GP depending on whether it was associated with a herbal remedy or a conventional OTC medicine. This has implications for herbal pharmacovigilance, particularly given the increasing use of OTC herbal remedies. The finding that a high proportion of respondents would not consult their GP or pharmacist following ADRs to conventional OTC medicines is also of concern.

Keywords: herbal medicines; drugs, non-prescription; drug monitoring; adverse drug reaction reporting systems; alternative medicine

Introduction

In the UK, herbal remedies (phytomedicines) are increasingly being used by the general public on a self-selection basis to replace or complement conventional medicines.¹ Recently, the UK market for licensed herbal medicines in 1996 was estimated to be worth £38 million, representing over half of the total market for complementary remedies.² However, since the majority of herbal remedies sold in the UK consists of unlicensed products, this is likely to be a gross underestimate.

One of the reasons for the popularity of herbal remedies is the belief among many users and suppliers of herbal remedies that these preparations are natural and, therefore, ‘safe’.¹ This, however, is a misconception - herbal remedies can produce adverse drug reactions (ADRs),^{3,4} some of which can be serious, even fatal.^{5,6} However, because users believe that such remedies are ‘safe’, individuals experiencing ADRs may not associate these with their use of herbal remedies.⁵ A further complication is that, in the UK, the majority of herbal remedies are self-prescribed,¹ and many individuals may be reluctant to tell their general practitioner (GP) that they are using them.⁵ Even if ADRs are reported by patients, their GPs may not be fully briefed about the use and effects (adverse or otherwise) of herbal remedies, and that systems exist for reporting ADRs to herbal remedies.

The European Union (EU) has commissioned research into this problem through its BIOMED (Biomedical and Health Research) programme *Determining European standards for the safe and effective use of phytomedicines*. As part of that programme, this study was designed to determine whether ADRs (“side effects”) to herbal remedies would be reported differently than similar ADRs to conventional OTC remedies, and to identify experiences of ADRs to herbal remedies and how they are perceived by consumers.

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Methods

Two types of outlet - Boots the Chemists Ltd (BTC) and Holland & Barrett (H&B), representing a pharmacy setting and healthfood store setting, respectively - were chosen. Interviews were conducted in six BTC stores with a high turnover of herbal remedies (Manchester, Leeds, Newcastle, Milton Keynes, London, Cardiff) and in six H&B stores near the selected BTC stores (Manchester, Leeds, Newcastle, Milton Keynes, London, Swansea).

Experienced interviewers, recruited and trained for this task by a market research company, were provided with study questionnaires, photographs and lists of examples of herbal remedies, other complementary remedies and conventional OTC medicines, and a list of examples of ADRs ("side effects"). These materials were used to assist interviewers and interviewees in identifying what was and what was not a herbal remedy (interviewers were instructed that consumers did not have to select remedies from the photographs/lists). The list of ADRs was used as a prompt if consumers were unsure what was meant by a "side effect", or if they answered that they had never experienced any "side effects" to herbal remedies. Interviewers were instructed to position themselves at an appropriate distance from the herbal remedies counter in the respective stores, and to approach customers who had purchased herbal remedies or those who had browsed the herbal remedies section. Customers were asked if they would be willing to be interviewed as part of a study on herbal remedies. Those agreeing to be interviewed were asked if they ever use herbal remedies; if they answered, "No" the interview was terminated. If a customer answered, "Yes", the interviewer continued with the questionnaire (written consent was not obtained); interviews took around eight minutes. All questionnaires were analysed at the University of Exeter.

The study was conducted in September, 1996. An interviewer was present in the selected stores on two consecutive days for eight hours per day in BTC stores, and four hours per day in H&B stores. The study was weighted more towards BTC customers than H&B customers to reflect market share.⁴

A structured questionnaire for customer interviews was designed and developed for this survey by researchers at the University of Exeter. Copies of the questionnaire are available on request.

Respondents were asked what herbal remedies and conventional OTC medicines they used, how often ("regularly" or "occasionally"), and for what condition. Respondents were also asked if they ever used vitamins, minerals or dietary supplements, or other "natural" health remedies (e.g. homoeopathic medicines, aromatherapy oils). Data on how respondents choose their herbal remedies and from where they obtain them, were also collected. In addition, respondents were asked if they had ever experienced any "side effects" after taking herbal remedies and, if so, were asked to provide the following details: name of herbal remedy; associated "side effect"; severity ("mild", "moderate" or "severe"); if they reported the "side effect" and to whom; if they stopped taking the remedy because of the "side effect". Respondents were also asked for demographic information (gender, age, occupation); social grade and ethnic group were assessed by the interviewer.

The key part of the interview sought to obtain information on what action respondents would take if they experienced a) a "serious side effect" (for the purposes of this survey, this was defined as "a symptom(s) that was worrying or alarming"), and b) a "minor side effect" (defined as "a symptom(s) that caused some discomfort, but was not alarming") to a conventional OTC medicine and to a herbal remedy. Respondents were allowed to select one or more of the following responses: continue taking [the preparation] and see if symptom(s) resolved; stop taking immediately; consult your doctor; consult your pharmacist; consult another health care practitioner; other action.

Prior to conducting the full survey, a pilot survey was conducted in the BTC store in Leeds where 32 herbal remedy users were interviewed by one interviewer.

Data from the full survey were analysed at the University of Exeter; the data from the pilot study were not included in the final analysis.

Results

Demographics and patterns of use

690 individuals agreed to be interviewed. Of these, 175 (25.4%) stated that they did not use herbal remedies and, therefore, these interviews were terminated. 515 face-to-face interviews with users of herbal remedies were conducted: 336 in BTC stores and 179 in H&B stores.

Females predominated (82% overall). The proportion of females interviewed in BTC stores was significantly greater than that in H&B stores (296/336 vs 127/179, respectively; $\chi^2 = 23.4$; $p < 0.001$). The ethnic origin of respondents was predominantly Caucasian (91%); Afro-Caribbean (2%), Indian/Pakistani (2%) and Chinese/Japanese (1%) ethnic groups were also represented. The age distribution of respondents was: < 20 years, 2%; 20-29 years, 15%; 30-39 years, 20%; 40-49 years, 24%; 50-59 years, 19%; 60 years, 20%. There were no marked differences in age distribution between the two types of stores.

Sixty-two percent of all respondents (58.0 and 68.2% for BTC and H&B respondents, respectively) used one or more herbal remedies *regularly*, whereas 38% (42.0 and 31.8% for BTC and H&B respondents, respectively) used one or more herbal remedies *occasionally* (respondents were allowed to name a maximum of three remedies). Eighty-one percent of all respondents (83 and 77% for BTC and H&B respondents, respectively) were also *regular* or *occasional* users of conventional medicines; 78% (79 and 77% for BTC and H&B respondents, respectively) stated that they used vitamins, minerals and/or food supplements; 49% (51 and 45% for BTC and H&B respondents, respectively) stated that they used other 'natural' health remedies (e.g. essential oils used in aromatherapy, homoeopathic remedies).

Respondents choose their herbal remedies (respondents were asked to indicate all relevant responses) on the basis of a friend's or family member's recommendation (31% of respondents), on the basis of their own knowledge (40%), by browsing (28%), on the basis of media advertising (14%), on the basis of a pharmacist's recommendation, on a prescription or recommendation from their doctor, and on the recommendation of, or supplied by, a herbal medicine practitioner (6% for each), and on the basis of another complementary-medicine practitioner's recommendation (7%). Further analysis reveals that 32 respondents (6% of total) choose herbal remedies on the basis of a doctor's, pharmacist's, or herbal practitioner's recommendation *alone*. By contrast, 427 (83%) choose *only* on the basis of one or more of the following: other complementary-medicine practitioner's recommendation; friend/family member's recommendation; own knowledge; media advertising; by browsing in shops; other basis. 56 (11% of total) choose on the basis of both the former and the latter.

The majority of respondents obtains herbal remedies from a pharmacy and/or healthfood store (64% and 54%, respectively; responses not independent); respondents also obtain herbal remedies from the following outlets: supermarket/grocery store (10%); by mail order (5%); garden/countryside (1%); other source (6%)

Likely behaviour upon experiencing ADRs

Table 1 shows the numbers of respondents who would take a particular course of action after experiencing a suspected ADR to a herbal remedy and to a conventional OTC medicine. The data are presented in a manner that allows the numbers of respondents who would act *differently* for ADRs to herbal remedies than for similar ADRs to conventional OTC medicines to be identified.

Following a serious ADR, 156 respondents (30.3% of all replies) would consult their GP irrespective of whether the ADR was associated with the use of a herbal remedy or a conventional OTC medicine; 221 respondents (42.9%) would not consult their GP for a "serious" ADR associated with either type of preparation. 134 respondents (26.0%) would consult their GP for a serious ADR to a conventional OTC medicine, but not for a similar ADR to a herbal remedy, whereas four respondents (0.8%) would consult their GP for a serious ADR to a herbal remedy, but not for a similar ADR to a conventional OTC medicine. Similar differences were found in the attitudes of herbal-remedy users towards reporting "minor" ADRs associated with herbal remedies and for similar ADRs to conventional OTC medicines.

Perceptions and experience of ADRs associated with herbal remedies

Thirty-one respondents stated that they had experienced ADRs to herbal remedies. However, seven of these reports referred to non-herbal complementary remedies. A further three reports cannot definitely be called herbals ('Vitalax', 'Keratine' and a product the name of which was written illegibly). Excluding the latter three reports gives a total of 21 respondents (4.1%) who reported having experienced an ADR associated with the use of a herbal remedy. Of these, three respondents rated the adverse effect as "severe", eight rated it as "moderate", nine rated it as "mild" and one entry was missing. Of the three reports rated "severe", one was said to have been reported to a doctor; two were not reported. In total, three of the 21 respondents who reported ADRs claimed to have informed their GP (we have not received replies to our letters attempting to verify these reports), 15 (73%)

Table 1.

Number of respondents (% of total) that would choose a particular course of action after experiencing a suspected ADR to i) a conventional OTC medicine and ii) a herbal remedy. Participants responded yes or no for each type of preparation. The four groups represent respondents who answered yes for both preparations, no for both, and those who gave different answers depending on whether the ADR was associated with a conventional OTC medicine or a herbal remedy.

Nature of ADR	Likely action following ADR	Type of decision			
		Yes for both	No for both	Yes for conventional; No for herbal	No for conventional; Yes for herbal
Serious†	Continue taking and see if symptom(s) resolved	11 (2.1%)	494 (95.9%)	1 (0.2%)	9 (1.7%)
	Stop taking immediately	327 (63.5%)	108 (21.0%)	18 (3.5%)	62 (12.0%)
	Consult GP	156 (30.3%)	221 (42.9%)	134 (26.0%)	4 (0.8%)
	Consult pharmacist	34 (6.6%)	440 (85.4%)	15 (2.9%)	26 (5.0%)
	Consult other health-care practitioner	9 (1.7%)	471 (91.4%)	0 (0%)	35 (6.8%)
Minor‡	Continue taking and see if symptom(s) resolved	98 (19.0%)	374 (72.6%)	11 (2.1%)	32 (6.2%)
	Stop taking immediately	268 (52.0%)	185 (35.9%)	21 (4.1%)	41 (8.0%)
	Consult GP	33 (6.4%)	405 (78.6%)	75 (14.6%)	2 (0.4%)
	Consult pharmacist	35 (6.8%)	454 (88.2%)	10 (1.9%)	16 (3.1%)
	Consult other health-care practitioner	8 (1.6%)	482 (93.6%)	0 (0%)	25 (4.9%)

† defined as a symptom(s) that was worrying or alarming;

‡ defined as a symptom(s) that gave some discomfort, but which was not alarming; ADR = adverse drug reaction

stopped taking the medicine concerned and six (27%) did not stop taking the preparation. One report associated with a non-herbal product (“*asthma symptoms*” associated with the use of Royal Jelly; classed as “severe”; reported to a doctor) gives cause for concern.

Discussion

This is the first study to provide evidence that herbal remedy users would be less likely to consult their GP for suspected ADRs (serious or minor) to herbal remedies than for similar ADRs to conventional OTC medicines. This has implications for herbal pharmacovigilance and implies that many suspected ADRs to herbal remedies will go unmonitored.

There may be several reasons for this finding. Herbal remedies are largely used on a self-treatment basis and some users may not realise that they can consult their GP about ADRs to such products. Others may be reluctant to admit herbal-remedy use to their GP by consulting him/her for suspected ADRs. In a study of unconventional medicine use involving 1539 adults in the US, Eisenberg *et al* reported that of 34% respondents who reported using at least one unconventional therapy in the previous year, 72% did not inform their doctor of their use of the therapy.⁷

Whatever the reason, the findings of the present survey raise concerns not only with regard to reporting of ADRs associated with herbal remedies, but also for those associated with conventional OTC medicines. Even for a ‘serious’ ADR, only 290 respondents (56.3%) would consult their GP; for ‘minor’ ADRs associated with conventional OTC medicines, only 108 respondents (21.0%) would do so. The present survey also appears to have uncovered an underutilisation of the pharmacist with regard to ADR reporting. For serious ADRs associated with herbal remedies, only 11.6% of respondents claim they would consult a pharmacist; for similar ADRs associated with conventional OTC medicines, 9.5% claim they would do so. Similar figures were obtained for minor ADRs.

Even those suspected ADRs which are reported to a GP and which meet ADR-reporting criteria may not be reported on to national pharmacovigilance centres. In the UK, hospital physicians have been shown to grossly under-report ADRs that meet CSM criteria;⁸ there is no evidence to suggest that GPs are any more diligent in this area. Furthermore, deficiencies in the reporting proc-

ess may be even more likely to occur with herbal remedies.⁵ The UK Medicines Control Agency’s (MCA) and Committee on Safety of Medicine’s (CSM) Yellow Card scheme already requests reports relating to suspected ADRs to all (i.e. both licensed and unlicensed) herbal remedies,⁹ yet (perhaps because they are not aware of this request) reporting by doctors is still limited.¹⁰ In April 1997, the MCA extended the Yellow Card scheme to include hospital pharmacists.¹⁰ Community pharmacists are seen as having a critical role in areas of limited reporting by doctors, e.g. over-the-counter medicines, and licensed and unlicensed herbal products.¹¹ However, at present, ADR reporting by community pharmacists is limited to those working in the four CSM monitoring regions (Liverpool, Newcastle, Cardiff, Birmingham).

There is an increasing awareness of the need to monitor the safety of herbal remedies.⁵ Our findings lend support both to the MCA/CSM decision to extend its Yellow Card reporting scheme to pharmacists, and to the European Scientific Co-operative for Phytotherapy’s (ESCO) pharmacovigilance system for herbal remedies (PhytoNet). In the latter, suspected ADRs to herbal remedies may be reported via a password-protected, Internet-based reporting system which is being targeted at all health professionals who use herbal remedies.

In conclusion, consumers of herbal remedies would act differently with regard to reporting an ADR (serious or minor) to their GP, depending on whether the ADR was associated with a herbal remedy or a conventional OTC medicine. This implies that many ADRs to herbal remedies may go unmonitored. Our findings illustrate the need for greater public awareness that ADRs to herbal remedies can occur, and that such events should be reported to an appropriate authority. Professionals also need to be aware of the potential for herbal remedies to cause ADRs and routinely question their patients about their use of such remedies. In the longer term, further research to investigate the safety and efficacy of herbal remedies is needed so that the risk/benefit ratio of using a particular herb for a specific condition can be determined.

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