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Adverse reactions to complementary medicines – the Australian pharmacy experience

Introduction

Australia has a two-tiered system of regulation for therapeutic products which is based on risk. Each low risk therapeutic product is given a unique AUST L number which indicates that its ingredients have been evaluated by the Therapeutic Goods Administration (TGA) for safety and classified as low risk. Nearly all over-the-counter (OTC) complementary medicines (CMs) contain listed (low risk) ingredients [1]. Despite these measures, no therapeutic substance can be entirely risk free.

Various countries, including Australia, have incorporated CMs into their pharmacovigilance systems to improve identification of CM-associated risks. However, the effectiveness of CM pharmacovigilance depends on the insight of everyone involved in taking, prescribing, dispensing and providing professional advice about CMs and the ability and willingness of all to report suspected adverse effects to the appropriate authorities [2].

Under-reporting of adverse drug reactions (ADRs) is a major limitation of all spontaneous reporting systems. Studies from North America indicate that formal reporting rates may be as low as 1.5% of total ADRs leaving many adverse reactions unidentified by this method [3]. It is likely that reporting rates of less severe ADRs are even lower leaving many mild to moderately severe side-effects undetected and a hidden source of patient morbidity.

Most pharmacies in North America and Europe sell CMs. In Australia, community pharmacy is the main place of purchase for CMs [4;5]. People attending these locations have ready access to pharmacists who are available to inform them about the risks of therapeutic products, give advice about potential drug interactions and identify and report suspected adverse reactions.

Methods

We conducted a survey of pharmacy customers randomly selected from metropolitan and rural pharmacies in three Australian states using a self-administered questionnaire which adopted and adapted questions from other surveys and also included new questions relevant to the study aims [4;6;7]. The primary aim was to determine the prevalence of adverse reactions to OTC CMs and their severity, as described by consumers. Secondary aims were to identify whether consumers reported the suspected reaction to a healthcare professional and their understanding of the AUST L designation on product labels.

Data collection took place between August 2008 and February 2009. Ethics approval was obtained from the Alfred and Monash Human Research Ethics Committee, and subsequently from Charles Sturt and Griffith Universities. A p-value of 0.01 was considered to be statistically significant.

Results

Among the 1121 respondents (response rate 62%) 72% had used a complementary medicine product in the previous 12 months, and 7% of this group (n=55) reported having experienced an adverse reaction at some time. The only health parameter with

a significant association was self-reported poorer health (p=0.0002) whilst no significant associations were found for age, gender, education, income, use of warfarin, digoxin or the oral contraceptive pill.

Of these 55 people, 71% described the reaction as mild and not requiring treatment, 22% as moderate and/or requiring advice from a healthcare professional and 7% (n=4) as severe and requiring hospitalisation. Additional questions about behavioural responses to the reaction revealed that 78% stopped using the suspected product, 13% sought advice from a healthcare professional, 13% changed products and 7% reduced their dose.

If customers were to report the adverse reaction to a healthcare professional, it was most commonly to a medical practitioner (see Figure 1).

The majority (88%) of customers that had taken CMs in the previous 12 months had never noticed the term 'AUST L' on a product label. Of those that had, 33% thought it meant the product was tested by a government agency for safety, 26% thought it was tested by a government agency for quality, and 24% thought it denoted an Australian made product, 15% it was tested by a government agency for effectiveness and 13% stated they did not know what it meant.

Discussion

These results suggest the prevalence of serious adverse reactions to CMs, as reported by Australian consumers, is relatively low compared to pharmaceutical medicines. Four people (0.49%) out of the total sample of CMs users reported having experienced an adverse reaction which required hospitalisation. Mild reactions were far more common. A similar finding was presented by Bensoussan et al. (2004) where naturopaths and Western herbalists reported the most common adverse reaction seen to herbal and nutritional medicines was mild gastrointestinal discomfort [8]. Whether this low figure is due to the inherent safety of OTC CMs ,the stringency of Australian regulation or other factors remains unclear.

Under-reporting of adverse reactions to pharmaceutical medicines is a well known problem and long suspected to be a problem with CMs also. This study identifies that many people experiencing a suspected adverse reaction to CMs do not inform their healthcare provider and some feel sufficiently confident to self-manage the situation. In this study, the majority of people chose to stop using the suspected product and many did not seek professional advice. Considering that most people self-select CMs or choose them based on advice from family or friends [9] it is not surprising they also choose to self-manage their adverse reactions when these are mild in nature.

Government authorities can improve patient safety by undertaking a consumer education campaign to encourage reporting of suspected adverse reactions to CMs and explain the significance of the AUST L designation. Disseminating safety information to all relevant health care providers, including CM practitioners is also essential. Pharmacists and other health care providers should be sufficiently knowledgeable about CMs so they can give patients informed advice about their safe and appropriate use and identify and report, in sufficient detail, any suspected adverse reactions.
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Whilst serious adverse reactions to CMs appear to be relatively rare, this study only provides an estimate of the true incidence of adverse reactions as causality could not be determined from the data obtained and customers are most likely to have identified obvious or acute adverse reactions. Further research is required to confirm these findings.

Conclusion

CMs are widely used by pharmacy customers. Adverse reactions to CMs are under-reported to healthcare authorities. Most adverse reactions to CMs are mild and serious reactions are rare.

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