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Over-the-counter codeine analgesic misuse and harm: characteristics of cases in Australia and New Zealand

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Abstract

Aim To describe the characteristics of clients addicted to over-the-counter (OTC) codeine analgesics presenting to an Auckland open-access clinic, and to compare them to clients admitted to a New Zealand detoxification unit, and in the Australian community.

Method Cross-sectional study of clients presenting to a regional, open-access detoxification clinic covering the Greater Auckland area between 1 January and 31 March 2010.

Results Fifteen clients were analysed, and compared to 77 similar clients identified in Victoria and five other Australian States, and 7 clients admitted to a New Zealand detoxification unit. Cases in each cohort were consistent with those in the published literature, and appear to be similar to each other both demographically and in terms of the high average tablets consumption (49–65 tablets per day), the serious non-steroidal anti-inflammatory drug (NSAID) adverse drug reactions identified, and the long duration of misuse. Many had a history of alcohol or other drug use and mental health disorder.

Conclusions This study has identified that controls on OTC codeine analgesics in both countries were not sufficient to limit non-medical use of these products. As a result, cases identified in these two countries escalated the number of self-administered tablets taken daily for misuse, resulting in codeine dependence and serious NSAID toxicity secondary to this dependence.

Internationally, the misuse of pharmaceutical drugs is a growing problem.[1] Whilst there is clear evidence of misuse of prescription drugs,[2] particularly those containing opioids, recent reports from the United Kingdom (UK),[3–5] Australia,[6–9] and New Zealand[10] indicate that there are also problems relating to misuse of over-the-counter (OTC) codeine analgesics.

The two main high-codeine content products available OTC in New Zealand are Nurofen Plus (codeine phosphate 12.8 mg and ibuprofen 200 mg) and Panadeine Plus (codeine phosphate 15 mg and paracetamol 500 mg).

This paper describes a study of clients identified prospectively presenting to a regional open-access detoxification clinic, and compares this population to their Australian and New Zealand counterparts.

Method

Over a 12-week period at the beginning of 2010, all clients presenting to an open-access detoxification clinic with a diagnosis of dependence on OTC codeine-

containing analgesics were identified. Details of the demographics, medications, codeine consumption patterns, associated morbidity, relevant history and management were recorded. The clinic covers the Greater Auckland region, involving three District Health Boards (Waitemata, Auckland, and Counties Manukau) with a combined population of approximately 1.4 million.

The clinic operates between 10am and 1pm Monday to Friday, and provides information, advice and support to individuals and families on detoxification from any substances. Comparisons were made between clients dependent on OTC codeine-containing analgesics, similar clients identified in Victoria and five other Australian states[6] and clients admitted to a New Zealand hospital detoxification unit.[10]

Results

Fifteen clients were identified (8% of all new attendances at the clinic). Details of these clients and their Australian and New Zealand inpatient counterparts are summarised in Table 1.

Table 1. Clients addicted to over-the-counter codeine products

Variables	New Zealand open access clinic	New Zealand detoxification unit[10]	Australia[6]
Number of cases	15	7	77
Male (%)	53	43	46
Average age (years)	44	44	33
Age range (years)	30–60	31–63	18–53
Aged <45 years (%)	53	43	95
Average daily intake of tablets	49	65	50
Daily intake codeine (mg)	627	832	640
Daily intake ibuprofen (grams)	9.8	13.0	10.0
Average duration of misuse (months)	27	22	30
Gastrointestinal bleeding/dyspepsia (%)	53	57	50
Renal tubular acidosis (%)	7	-	9
Alcohol or other drug use (%)	53	86	38*
Mental health disorder (%)	93	57	28*

*Many of the case reports did not provide information about this aspect of the medical history.

Amongst the New Zealand Auckland clinic clients, 66% had recently been hospitalised due to intoxication and/or physical problems associated with their OTC codeine preparation use. Of the 15 clients identified at the clinic, 47% undertook a community-based detoxification, 27% an inpatient detoxification, 13% self-detoxed and 13% were referred for methadone maintenance treatment.

Discussion

Although the three populations identified in Table 1 are not directly comparable, there appears to be many similarities between them (age range, average daily intake of tablets, average duration of misuse and associated gastrointestinal problems). A substantial proportion of the clients in the two New Zealand studies had a history of alcohol or other drug use and mental health disorders.

There was also a high prevalence of opioid dependence, consistent with cases published in the literature and in the Australian cohort. As would be expected from the large quantities of ibuprofen being ingested, more than half of the clients in the three surveys presented with gastrointestinal bleeding or dyspepsia.

These findings suggest that misuse and harm from combination codeine analgesics may be a growing problem in countries where they are available OTC. There are no official statistics for the UK but two websites have been identified which have over 4,000 people self-reporting having codeine dependency.[3] An Australian web-based online survey identified 180 recent users of OTC codeine, 17% of whom were classified as being codeine dependent (using the Severity of Dependence Scale)[4].

Despite this evidence there is considerable resistance from the pharmaceutical industry to further restrictions on sales of OTC codeine products. In a submission to the Medicines and Medical Devices Safety Authority's (MEDSAFE) Medicines Classification Committee, the New Zealand Self Medication Industry Association stated that it "believes that the needs and interests of the vast majority of responsible consumers need to be balanced against the risks of harm to a very small number of individuals".[11]

Similar arguments have been put forward in the past relating to temazepam capsules, flunitrazepam (Rohypnol) and paracetamol/dextropropoxyphene (Paradex). More explicit reasons have been given by an industry consultant in Australia: "This analgesic category generates almost the highest gross profit margin of all the categories in your pharmacies. It is an area definitely worth defending. There are some dollars at threat (average loss of $17,000 per pharmacy per year").[12] Last year OTC codeine products accounted for AU$84 million sales in Australia[12] and NZ$13 million in New Zealand.[13]

As awareness of the problems of OTC codeine preparations has grown, regulatory authorities have been examining their policies. In September 2009, the UK Medicines and Healthcare products Regulatory Agency (MHRA) updated its advice on non-prescription medicines containing codeine or dihydrocodeine.[14] The MHRA recommended that warnings on labels and leaflets should be further clarified and strengthened—*Can cause addiction. For 3 days use only*, pack size be restricted to 32 tablets, and that the existing advertising self-regulatory code should be strengthened.

In Australia, the National Drugs and Poisons Schedule Committee (NDPSC) recommended that from May 2010 OTC codeine analgesics be rescheduled to pharmacist only, thus preventing advertising to the public and self-selection in the pharmacy, and that pack sizes should be reduced to 30 tablets.[15]

In New Zealand, MEDSAFE's Medicines Classification Committee recommended that from 4 October 2010 pack sizes should be reduced to 30 tablets, and there should be behind the counter sales only. Sales should be restricted to qualified pharmacists, and warnings on labels should be strengthened—*Risk of addiction. Do not use for more than 3 days unless on medical advice* (from 1 May 2011).[16]

Although these responses are laudable, the lack of supportive pharmacological evidence for combinations of lower-dose codeine in compound analgesics, and the risk of adverse effects,[10] have prompted some authorities, including the United States' Food and Drug Administration's Acetaminophen (paracetamol) Advisory Committee,

and a leading US gastroenterologist, to question the continuing availability of non-prescription and prescription acetaminophen (paracetamol)/opioid combination products.[17,18] If recent tightening of the regulations in New Zealand, Australia and the UK does not have an impact on the trends described in this article, more drastic measures may need to be considered.

There is limited evidence of analgesic benefit from the incorporation of low-dose codeine into combination analgesics. As noted by Ferner and Beard, there are "disadvantages when relatively safe and effective analgesics such as paracetamol and ibuprofen are combined with small doses of an opioids that are likely to bring trivial therapeutic benefit, but increase the risks of abuse, addiction and adverse effects".[19]

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