Sedative Hypnotic Use in Alberta

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Objective: Benzodiazepines and similar sedative-hypnotics (BDZ-SSHs) are associated with both beneficial and adverse effects. Pharmacoepidemiologic data describing the use of these medications in contemporary Canadian populations has not been readily available. Our objective was to examine the hypothesis that increasing use of antidepressant medications for anxiety and mood disorders during the past decade led to less frequent use of BDZ-SSH medications.

Method: We used data from an Alberta Mental Health Survey to describe the pattern of BDZ-SSH use and to estimate provincial and health region frequencies of use. We supplemented the data with pharmacy dispensing data from IMS Health.

Results: The frequency of use was comparable to that reported in previous studies. Unexpectedly, in the survey data, we observed trends suggesting regional variation both in the frequency and pattern of use. Examination of prescription dispensing data confirmed this pattern. Clinical factors, including the use of other psychotropic medications and psychiatric diagnoses, were strongly associated with BDZ-SSH use. Among the drugs examined, zopiclone had the highest frequency of use. Prescription dispensing data confirmed that the frequency of zopiclone use in Alberta is higher than that in most other provinces.

Conclusions: This descriptive study generates several new research questions and provides benchmarks for future pharmacoepidemiologic monitoring.

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Clinical Implications

- Regional differences exist within Alberta and across Canadian provinces in the use of BDZ-SSH drugs.
- The frequency of BDZ-SSH use increases with age.
- In Alberta, zopiclone is now the most frequently used hypnotic drug.

Limitations

- The survey component of this study relied on self-reported drug use data.
- The survey component of this study used random digit dialing, which results in underrepresentation of institutionalized and homeless individuals.
- Prescription dispensing data cannot confirm that purchased drugs were actually consumed.

Key Words: epidemiology, cross-sectional studies, sedative-hypnotic medications, mood disorders, anxiety disorders, population studies.

Pharmacoepidemiology is the study of medication use in real world populations. Pharmacoepidemiologic studies provide an opportunity to monitor therapeutic trends. During the past 2 decades, antidepressant medication use has increased in Canada (1) and other countries (2–5). Hypothetically, more effective treatment of mood and anxiety disorders could lead to a reduction in the use of sedative-hypnotic medications as symptomatic treatments for insomnia and anxiety.

Further, the pattern of use in different population subgroups may change over time. In Alberta, the AMHS was conceived as a vehicle to monitor mental disorder prevalence as well as the frequency and adequacy of pharmacotherapy for mental disorders in the population. Data from this survey are useful in addressing key questions: What is the frequency of use of various classes of medication in the population? What factors are associated with a higher or lower frequency of use? This analysis presents estimates from the AMHS, supplemented by additional drug sales data from IMS Health Canada (www.imshealthcanada.com).

BDZ-SSHs are frequently prescribed. Collectively, these medications have a broad range of activity that includes anxiolytic, hypnotic, sedative, and anticonvulsant properties, with indications that vary by product, including anxiety disorders, insomnia, alcohol withdrawal, and skeletal muscle spasticity. In addition to their therapeutic properties, BDZ-SSHs are associated with adverse effects, including drowsiness, an increased risk of falls in the elderly, an increased frequency of motor vehicle accidents, dependence, and abuse (6–9).

The pharmacoepidemiology of BDZ-SSH use in contemporary Canadian populations has been inadequately described. The most extensive analysis was conducted and reported in 1991 by Rawson and D'Arcy (10). They used data from several large national and regional surveys, all of which used omnibus questions in which individuals were asked whether they were taking categories of medications such as sleeping pills, tranquilizers, or sedatives. The proportions reporting use within the preceding 2 days ranged from 4.9% to 6.1%. An elevated frequency of use was found in women and in association with advancing age, unemployment, and lower income levels. The findings for marital status and education were

complex; interactions with other demographic variables were reported.

The disproportionate frequency of use in elderly individuals may have policy implications in view of reports linking benzodiazepine exposure to motor vehicle accidents (11), hip fractures (12,13), cognitive problems, and self-care limitations (8) in the elderly age group. The increased risk of injury owing to traffic accidents may not be restricted to the elderly age group, however (14,15). Benzodiazepine use can lead to dependence (16,17) and may be a contributing factor in fatal overdoses (18).

Busto and colleagues (20) examined drug sales data, using the DDD system. This study found that overall benzodiazepine use in Canada remained consistent from 1978 to 1982 at 33 DDD/1000 inhabitants daily. However from 1983 onwards this increased, reaching 48 DDD/1000 inhabitants daily in 1987. Long half-life benzodiazepine use decreased from 91% of total benzodiazepine use in 1978 to 39% in 1987, whereas short half-life benzodiazepines increased from 9% to 61% during this time period.

Zopiclone, a cyclopyrrolone derivative, and zaleplon, a pyrazolopyrimidine, are nonbenzodiazepine sedative-hypnotics that share some pharmacologic properties with benzodiazepines, potentially including many adverse effects and risks (20–24). Both zopiclone and zaleplon are listed under Schedule IV of the International Narcotics Control Board green list, (www.incb.org/pdf/e/list/green.pdf). Neither zopiclone nor zaleplon, however, is classified as a controlled drug in Canada, whereas the benzodiazepines are. Descriptive pharmacoepidemiologic information about these medications in Canada during the past decade has not been available.

In this paper, benzodiazepines, zopiclone, and zolpidem are grouped together, for most analyses, into a category designated BDZ-SSHs, with the proviso that zopiclone and zaleplon are probably not used commonly as anxiolytics. We did not include other pharmacologically distinct and less commonly used sedative agents (for example, chloral hydrate), anxiolytics (for example, buspirone), or drugs with other primary indications (for example, diphenhydramine, doxylamine, and trazodone) to keep the focus of the analysis more manageable.

In this analysis, we hypothesized that the frequency of use of BDZ-SSHs decreased from that previously reported. We sought to determine whether an increased frequency of use has continued to occur in relation to increasing age, lower income, and unemployment.

Abbreviations used in this article

ATC	anatomic therapeutic code
AMHS	Alberta Mental Health Survey
BDZ-SSH	benzodiazepine and similar sedative-hypnotic
CI	confidence interval
DDD	defined daily dosage
EQ-5D	EuroQol quality of life measure
ICS-MCU	International Collaborative Study of Medical Care Utilization
CHS	Canada Health Survey
MINI	Mini-International Neuropsychiatric Interview
OR	odds ratio
RDD	random digit dialed
TEU	total extended unit

Method

The AMHS was the main data source used for this study. The AMHS collected data by telephone interview from a sample of Albertans aged 18 to 64 years. Initially, a random sample was drawn from an electronic file containing listed residential phone numbers. To ensure representation of nonlisted numbers, the last digit was altered by adding one. A total of 29 941 such phone numbers were called according to a protocol that included at least 3 daytime, 3 after-hours, and 3 weekend attempts. There was no contact with 15 092 numbers, including 11 694 numbers that were clearly not eligible (that is, not in service, businesses, and fax machines). There were also 3398 calls made to individuals whose eligibility could not be confirmed by direct contact—numbers that were continuously busy, calls that only reached answering machines, or calls that were not answered. At 376 numbers, we reached eligible individuals who had not been contacted through the call-back protocols at the time the study was terminated. Of households contacted, 2644 contained no eligible individuals. Owing to language barriers or interruptions, 593 interviews were not completed. There were 4512 household refusals and 1314 individual refusals. Of 7122 households in which eligible individuals were identified, 5410 participated in an interview and 5383 completed the entire interview, for an individual response rate of 76%. The individual response rate is 77% if we exclude from the response-rate denominator those who had not yet been contacted at the time of study termination .

The sample was stratified such that about 600 respondents aged 18 to 64 years were interviewed in each of the 9 health regions. The last-birthday method was used to select one individual from contacted households. The survey interview included modules (that is, dysthymia, major depression, bipolar disorder, panic disorder, agoraphobia, generalized anxiety disorder, and social phobia) from the MINI (25,26) to provide an indication of diagnostic status. Clinical significance criteria were applied to the MINI diagnostic output by means of an item assessing interference with usual activities similar to the ones described by Narrow and others (27). The interview included various other brief instruments such as a demographic module; the EQ-5D, a quality of life measure (28); and a pharmacoepidemiology module that recorded ATCs for all psychotropic medications being taken at the time of the interview (current use). Sampling weights were calculated to adjust for sampling method (that is, stratified sampling by health region, number of eligible adults in each household, and number of telephone lines) and nonresponse. Relative to aggregate data from the Alberta Health and Wellness Stakeholder Registry (www.gov.ab.ca), which were used in the weighting, men and certain age groups were underrepresented.

The sampling weights were incorporated into the analysis using the STATA (Stata Corporation, 2003) survey analysis commands. The data collection protocol for the AMHS was approved by the University of Calgary Office of Medical Bioethics. The telephone script for obtaining consent followed a format recommended by the Bioethics Office (www.fp.ucalgary.ca/medbioethics/download.html).

The interviews were conducted by trained and experienced telephone interviewers using computer-assisted telephone interviewing hardware and software. Interviews typically lasted about 20 minutes, but this varied because of the branched nature of the MINI interview. The number of questions asked in any given interview varied depending on individuals' responses to MINI screening items. The interviewers were not clinicians and were taught to administer the MINI as a fully structured interview. Training included a series of supervised mock interviews. Supervisory staff were able to monitor interviews to assure quality. The interviewers did not disclose MINI results to the individuals or intervene when suicidal ideation was reported. If they requested it, individuals were offered appropriate information about contacting mental health services.

When the survey results suggested regional variations, a second source of data, IMS Health Canada (www.imshealthcanada.com), was sought to obtain confirmatory evidence from an association. IMS Health monitors prescription dispensing from a representative sample of community pharmacies across Canada. IMS Health data can be linked to geographical reference areas such as health region boundaries. IMS Health provided estimates of the total number of prescriptions dispensed in Alberta in 2004, and also the number of doses (for example tablets or capsules) of each medication, or TEU of BDZ-SSH per capita in the 9 health regions. Since the TEU represents a number of pills or capsules, the TEU per capita estimates were rounded to the nearest whole number for presentation. Health region population data from 2002 (www.statcan.ca) were used as the denominator for calculating per capita dispensing.

Results

The total sample of the AMHS was 5383. The mean age was 40.8 years, SD 12.1. The sample comprised 2087 men (38.8%) and 3296 women (61.2%). Subsequent weighting adjusted for the overrepresentation of women in the sample. The overall frequency of BDZ-SSH use in Alberta was 3.0% (95%CI, 2.5% to 3.4%). The estimated frequency of zopiclone use was 1.5% (95%CI, 1.2% to 1.8%). One-half of all individuals taking a BDZ-SSH were taking zopiclone, but none were taking zaleplon. Another 17 individuals, a weighted frequency of 0.3% (95%CI, 0.2% to 0.5%), were taking trazodone. Possibly, many of these individuals were

Table 1 Frequency of BDZ-SSH use by demographic variable		
Variable	%	95%CI
Sex		
Men	2.0	1.4 to 2.6
Women	3.8	3.2 to 4.5
Age (years)		
18 to 24	0.9	0.2 to 1.5
25 to 34	1.4	0.7 to 2.1
35 to 44	2.7	1.9 to 3.6
45 to 54	4.9	3.8 to 6.1
55 to 64	5.0	3.4 to 6.6
Marital Status		
Married or common-law	2.5	2.0 to 3.1
Single, separated, divorced, or widowed	3.6	2.8 to 4.5
Employment status		
Employed (full-time)	2.1	1.6 to 2.6
Employed (part-time), contract work	3.6	2.2 to 4.9
Homemaker, student, on leave, or other	2.7	1.6 to 3.8
Unemployed, on disability, on social assistance,	10.8	7.4 to 14.2
Retired	6.7	3.1 to 10.3
Education		
Low education	2.8	2.1 to 3.4
High education	3.3	2.7 to 3.9

taking the medication as a hypnotic, since only 4 of these individuals reported a dosage over 150 mg. These individuals are not included in the subsequently presented estimates of BDZ-SSH use.

Table 1 shows the frequency of BDZ-SSH use in relation to sex, age, marital status, employment status, and education. More women reported using BDZ-SSHs than men. Those aged 45 years and over also tended to use these medications more frequently than younger groups. Those who were disabled, unemployed, on social assistance, or retired also had a higher frequency of use. The frequency increased about sixfold for those who were disabled, unemployed, or on social assistance, compared with those individuals who were employed.

In logistic regression analysis, neither the education variable nor any associated interactions were significant. When education was removed from the model, the effect of sex, age, marital status, and employment all remained significant. The adjusted OR for women was 2.0 (95%CI, 1.4 to 2.8). The adjusted OR for single, divorced, widowed, and separated marital status was 1.7 (95%CI, 1.2 to 2.3). For the disabled, unemployed, on social assistance employment category, it was 3.8 (95%CI, 2.5 to 5.7).

Table 2 shows the frequency of BDZ-SSH use among AMHS respondents in the 9 health regions of Alberta. The highest frequency of BDZ-SSH use was found in the Capital Health Region (Region 6). This is a central Alberta health region that includes the urban centre Edmonton. Compared with the Calgary Health Region (Region 3), which includes the urban centre Calgary, the Capital Health Region had an about 50% higher frequency of BDZ-SSH use; however, the estimates were not sufficiently precise to confirm the existence of a regional difference. The next-highest frequency of use was in the Palliser Health region, in the South Eastern corner of the province.

Table 3 shows the frequency of BDZ-SSH use in relation to diagnoses of mental disorders in the Alberta population according to the diagnostic categories identified by the MINI interview. The frequency of use was elevated for mood and anxiety disorders, but the frequency of use in individuals with substance use disorders was only slightly elevated. Consistent with the survey data, only 0.5% of TEUs for BDZ-SSH were for zaleplon, while 43% were for zopiclone.

As shown in Table 4, those reporting use of BDZ-SSH were more likely to report having problems in mobility, self-care, usual activities, pain or discomfort, and anxiety or depression

Figure 1 TEUs per capita in Canadian provinces
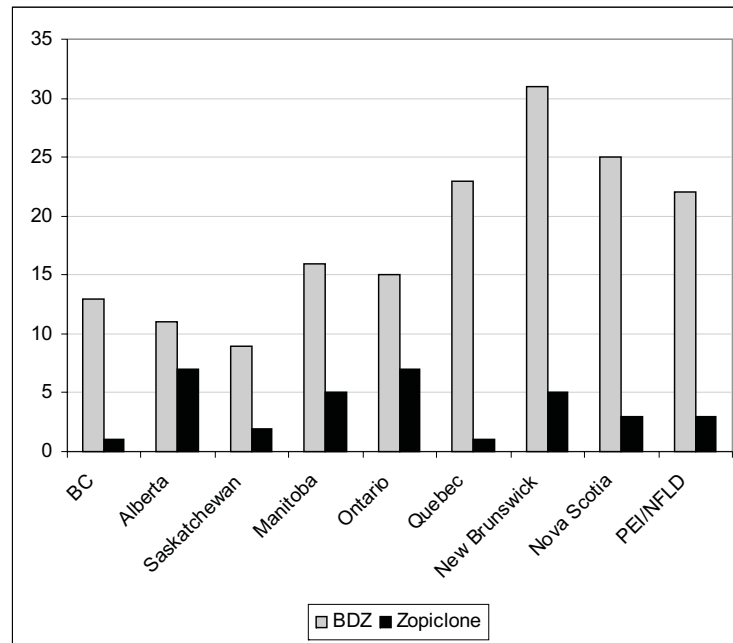
BDZ = benzodiazepine and similar sedative-hypnotic; NFLD = Newfoundland and Labrador;
PEI = Prince Edward Island

Table 2 Frequency of use and TEUs for BDZ-SSH, by health region in Alberta[a]					
		AMHS		IMS data	
	n	%	95%CI	Regional population[b]	TEUs[c]
Region 1, Chinook Health Region	600	3.0	1.6 to 4.4	152 021	16
Region 2, Palliser Health Region	598	3.7	2.1 to 5.3	97 080	32
Region 3, Calgary Health Region	597	2.7	1.4 to 4.1	1 107 165	15
Region 4, David Thompson Health Region	599	3.3	1.6 to 4.9	295 618	24
Region 5, East Central Health Region	597	3.1	1.6 to 4.5	111 514	20
Region 6, Capital Health	598	4.4	2.5 to 6.3	982 788	22
Region 7, Aspen Regional Health	597	3.1	1.7 to 4.5	175 614	18
Region 8, Peace Country Health	598	2.0	0.9 to 3.1	128 573	13
Region 9, Northern Lights	598	2.4	0.9 to 4.0	65 959	14

[a]Weighted estimates
[b]2002 estimates
[c]TEUs per capita

on the EQ-5D, compared with those who did not report the use of such medications.

Table 5 shows the frequencies with which individual BDZ-SSHs were used in individuals reporting use of one or more of these medications. The highest frequency of use was zopiclone, 47.4% (40.0% to 54.9%) followed by lorazepam, 28.7% (22.0% to 35.6%). Clonazepam, a long half-life benzodiazepine, had the third highest frequency of use.

Table 2 summarizes estimates according to the IMS data. The TEUs per capita of BDZ-SSH medications had an overall correlation with the AMHS data (Spearman's rho = 0.75, P = 0.019). The highest TEUs per capita were found to be in the Capital and neighbouring Central Alberta Health Regions and

Table 3 Frequency of BDZ-SSH use by current diagnoses according to the MINI[a]		
Diagnosis	%	95% CI
No mood, anxiety, or substance use disorder	2.2	1.8 to 2.6
Any mood disorder	14.0	10.0 to 18.0
Any anxiety disorder	16.4	12.1 to 20.7
Any substance use disorder	5.3	3.0 to 7.6

[a]with application of clinical significance criteria based on items assessing interference of symptoms with activities

Table 4 Frequency of quality of life impairment by BDZ-SSH use		
EQ-5D dimension	BDZ-SSH use (%)	No BDZ-SSH use (%)
Mobility	34.7	11.1
Self-care	14.3	2.5
Usual activities	43.8	11.5
Pain or discomfort	63.0	36.7
Anxiety or depression	38.5	15.8

the Palliser Health Region, although Palliser considerably exceeded the central Alberta regions, according to the IMS estimates. The higher TEUs per capita, such as in Palliser, reflect either a higher frequency of prescriptions, larger prescription size, or both. Alternatively, as the TEU data refer to the whole population and the survey data were for people aged 18 to 64 years, a different pattern of use in elderly individuals may also explain these differences.

There was evidence of regional differences in zopiclone use, with the Palliser Health Region having the highest frequency of use at 14 TEUs per capita in 2004. In the AMHS, the frequency of zopiclone use was 1.7%. In comparison, the lowest TEUs per capita for zopiclone were observed in the 2 most northerly regions: 4.6 and 3.3 TEUs per capita in the Peace Country and Northern Lights Regions, respectively, where reported frequencies of use in the AMHS were 0.8% and 0.9%, respectively. Figure 1 presents IMS Health estimates of TEU per capita for the Canadian provinces. The number of doses per capita dispensed for zopiclone appears to be higher in Alberta than in other provinces.

Discussion

The overall frequency of current sedative-hypnotic use according to the AMHS in Alberta was 3.0%, a figure lower than that reported by Rawson and D'Arcy for previous 2-day use according to ICS-MCU or CHS (10). The measures employed in the 2 studies, however, were not necessarily comparable. The pattern of association of BDZ-SSH use with

demographic variables was broadly consistent with that reported by earlier studies. Previous Canadian population studies have not been able to identify specific agents. The emergence of zopiclone as the most commonly used hypnotic in Alberta has also not previously been reported. As a province-wide monitoring activity, the AMHS was concerned with possible regional differences and therefore employed a sampling strategy that was stratified by health region. No statistically significant differences were observed among regions, but IMS Health prescription dispensing data, which confirmed the pattern. Taken together, the data suggest the existence of regional differences, with a higher frequency of use in a southern region, the Palliser Health Region, and several central Alberta health regions.

According to the AMHS, the frequency of BDZ-SSH use was higher in those who had mood or anxiety disorders. This is not an unexpected result as these medications are used in the management of the symptoms associated with these disorders.

The higher frequency of BDZ-SSH use in individuals reporting problems likely to be linked directly to disturbances of mental health (especially mood and anxiety) on the EQ-5D was similarly not unexpected. Notably, however, those reporting the use of these medications also reported more problems with mobility and usual activities. This is potentially important because those with mobility problems may be at an increased risk for falls, one of the public health concerns associated with the use of these medications.

Table 5 Frequency of individual BDZ-SSH use in the AMHS	
BDZ-SSH	%
Alprazolam	6.4
Clonazepam	10.1
Chlordiazepoxide	1.8
Diazepam	6.0
Flurazepam	0.1
Lorazepam	28.7
Nitrazepam	1.6
Oxazepam	1.5
Temazepam	3.6
Triazolam	0.1
Zopiclone	47.4

As an RDD survey, the AMHS is potentially vulnerable to both selection and measurement bias. The response rate was < 80%, and the male-female imbalance in the unweighted sample raises the possibility that survey respondents differed from nonrespondents in some way that affected the estimates. Also, the AMHS results are not generalizable beyond the age group surveyed, nor are they generalizable to institutionalized or homeless populations. Also, to the extent that mental illness and psychopharmacological drug consumption may be stigmatized, the frequency of use was possibly underestimated.

The AMHS included only individuals aged 18 to 64 years, which is the most notable among the potential sources of bias. The frequency of BDZ-SSH use is higher in those aged 65 years or over; therefore, it is possible that the overall frequency of use of these medications was underestimated in the Alberta population.

In the past decade, there have been various changes that might have been expected to produce a decline in the use of BDZ-SSHs. These changes include increased awareness of depressive disorders, which possibly resulted in more focused treatment for symptoms such as insomnia and anxiety. There has also been an increased awareness of nonpharmacologic strategies for managing insomnia, depression, and anxiety symptoms. Additionally, there have been dramatic increases in the frequency of antidepressant use (29). At the same time, as many BDZ-SSH medications have become generic, there has possibly been less marketing of these medications. All these factors were expected to cause a diminished frequency of use of these medications in the population. However, the frequency of use and demographic pattern of use were found to be similar to that of previous decades, with the provision

that, at least in Alberta, there has been a change in the frequency of use of specific agents—zopiclone is now the most frequently dispensed hypnotic agent.

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Résumé : L'utilisation de sédatifs hypnotiques en Alberta

Contexte : Les benzodiazépines et les sédatifs hypnotiques semblables (BDZ–SHS) sont associés à des effets tant bénéfiques qu'indésirables. Les données pharmaco-épidémiologiques décrivant l'utilisation de ces médicaments dans les populations canadiennes contemporaines ne sont pas facilement disponibles. Nous avons émis l'hypothèse que l'utilisation croissante d'antidépresseurs pour les troubles anxieux et de l'humeur au cours de la dernière décennie peut avoir entraîné une fréquence d'utilisation plus faible des BDZ–SHS.

Méthode : Dans cette étude, nous avons utilisé les données d'une enquête sur la santé mentale en Alberta pour décrire le modèle d'utilisation des BDZ–SHS et estimer les fréquences d'utilisation à l'échelle de la province et de la région sanitaire. Les données ont été complétées par les données d'IMS Health sur les pharmacies exécutant les ordonnances.

Résultats : La fréquence d'utilisation était comparable à celle rapportée dans les études précédentes. Inopinément, des tendances suggérant une variation régionale de la fréquence et du modèle d'utilisation ont été observées dans les données de l'enquête. L'examen des données sur l'exécution des ordonnances confirmait ce modèle. Les facteurs cliniques, incluant l'utilisation d'autres psychotropes et les diagnostics psychiatriques étaient fortement associés à l'utilisation des BDZ–SHS. Parmi les médicaments examinés, la zopiclone était le plus fréquemment utilisé. L'examen des données sur l'exécution des ordonnances confirmait que la fréquence d'utilisation de la zopiclone en Alberta est plus élevée que celle de la plupart des autres provinces.

Conclusions : Cette étude descriptive donne lieu à plusieurs nouvelles questions de recherche et fournit des repères à la future surveillance pharmaco-épidémiologique.