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The frequency of herbal medications and supplements in a series of
medical examiner scene investigations

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Abstract:

Complementary and alternative medicine use has been increasing worldwide. Although many studies have attempted to elucidate the levels of herbal medicine use in certain communities, many factors have led to limitations on the data collected. Self-report surveys are currently the only studies that have been done to quantify the actual use of herbal medications to date. This project uses a more comprehensive and objective means of examining the use of herbal medications in the state of New Mexico. Data from deaths investigated by the New Mexico Office of the Medical Investigator were examined to determine a more accurate picture of herbal use in New Mexico. Examining 1,112 deaths investigated during the first six months of 2006, we found that 5% of deaths had herbal medications or supplements present within the residence, with 4.6% having 3 or more supplements. Decedents with three or more prescription/OTC drugs found at the death scene were 3.03 times more likely to have three or more supplements as well, compared to those with two or fewer prescription/OTC drugs found on scene. The most commonly identified health complaints of patients in this study were hypertension, cardiac conditions and diabetes. Although the study was possibly limited by variations in the collection of data at scene investigations, the potential adverse interactions of herbal supplements with other medications warrants additional investigation.

Introduction

Recently, the use of complementary and alternative medicines (CAM) has increased around the world.¹ CAM includes a diverse group of medical practices and products that are not included in the realm of conventional medicine. Examples of CAM modalities include biofeedback, massage, acupuncture, meditation and the use of herbal medications and other supplements. Specifically, the use of herbals has increased over the last 15-20 years.¹ A national survey conducted between 1990 and 1997 demonstrated an 8% increase in CAM use during those years, with herbal medicine being one of the most increased modalities.² Along with the rise in use of herbals, there is also the rise in a possibility of their concurrent use with medicines composed of synthetic chemicals.³ This potential for the interaction between herbs and prescription drugs is of concern because the pharmacokinetic characteristics of one or more medications taken simultaneously can be altered and can lead to clinically significant toxicities. Over 100,000 deaths each year can be attributed to adverse drug interactions, and it has been suggested that many of these deaths could be linked to the use of herbs.⁴

Patients are using herbal medications more frequently for several reasons. Many are unhappy with the allopathic therapies suggested by their physicians, some want to become more active in their own health care, and yet others find

traditional western medicine does not fit into their own belief systems.⁴

Whatever the reason for utilizing herbal therapies, the fact remains that most patients do not discuss the use of alternative modalities with their physicians. In several self report studies, less than 45% of patients and care givers reported discussing the use of herbal remedies with their doctors.^{2,5,6} In one study conducted in a pediatric Emergency Department, 77% of parents who admitted to giving their child an herbal home remedy within the last year did not believe or were uncertain if herbal products had any side effects. Sixty-six percent were unsure or thought that herbal products did not interact with over-the-counter (OTC) or prescription medications.⁵ A large portion of the public does not discuss the use of herbal remedies with a doctor for precisely these reasons. Many believe that because herbal remedies are marketed as “natural” they are inherently safe.^{7,8} Herbals are seen as “different” from prescription drugs. The reality is, however, that plant-based drugs can be just as toxic as synthetic drugs if they are improperly used.

Toxicity from the use of herbal products can stem from contamination of the product, either accidental or deliberate, or simply due to manufacturer negligence.¹ Herbal products have been found to be contaminated with lead, mercury, cadmium, pesticides and microorganisms.¹ There is also the potential of variability in the concentrations of plant material within a given product. Variability in concentration stems from the use of different extraction and processing techniques by different manufacturers and can cause marked variability in the quality and in the content of products that are marketed as

having the same content. Only some manufacturers have begun to produce standardized extracts.⁸

Contamination and lack of standardization become a larger problem when the lack of regulation of herbal products is considered. In the US, herbal medications are classified as dietary supplements, excluding them from the regulations that govern OTC and prescription drugs. The lack of regulation means that herbals do not need approval from the Food and Drug Administration before they are marketed. This provides patients with access to multiple herbal medicines that have not been tested for safety and efficacy by preclinical studies and clinical trials.⁷ Herbal product regulation does fall under the Dietary Supplement Health and Education Act of 1994. This act requires producers to ensure safety and appropriate labeling of a product. Manufacturers and distributors are not, however, required to actually demonstrate the safety or efficacy of the product before placing it on the market. There lies a disparity between ensuring but not actually demonstrating the safety of a product, which leads consumers to have a false sense of security. Regulation of herbal products by the FDA occurs only after reports of adverse reactions are made about products already on the shelves.⁵

Many interactions and contraindications have been documented for herbal preparations. One of the most common interactions includes patients taking warfarin or aspirin who are also taking cod liver oil, evening primrose oil, ginkgo biloba or garlic. All of these natural remedies have coumarinic constituents and can increase the risk of bleeding.⁹ Ginseng has estrogen-like activity and can

interact with phenelzine and warfarin (causing a decreased International Normalized Ratio, or INR, which is an indirect measure of fibrinogen and clotting ability).^{1,4} One of the most commonly taken herbal remedies, St. John's Wort, an inducer of cytochrome p450, has been reported to reduce the plasma concentrations of cyclosporine, indinavir, ethynylestrodiol, theophylline, digoxin and warfarin.^{3,4} In fact, many of the adverse reactions seen when herbals are combined with prescription drugs are due to either inhibition or induction of CYP isoforms (drug metabolizing enzymes), by the herbs.³

Several studies have attempted to document the prevalence of herbal medicine use. Lanski et al looked at a sample of patients at a pediatric emergency department to determine the amount of herbal use within this population.⁵ Eisenberg et al conducted a national phone survey to document trends in alternative medicine use across the United States.² Barnes et al used interviews to determine whether adverse drug reactions to herbal remedies would be reported differently from similar reactions to conventional OTC remedies. They found that only 30.3% of the respondents would report adverse reactions regardless of whether it was associated with an herbal remedy or an OTC drug.⁶

All of these studies provide valuable information about the use of herbal remedies around the world. They are, however, limited in the part of the population that they are able to explore. All of the above studies were self-report surveys. Participants were excluded if they were not able to communicate in English in the both the Lanski and the Eisenberg studies; no mention of language was made in the Barnes study.^{2,5,6} The Lanski study also excluded critically ill

patients, and the Eisenberg study excluded any patients without a household phone. While these are understandable constraints upon the design of the studies, a more comprehensive look at herbal use is needed. It is probable that the populations excluded from the previous studies (non English speakers, and the impoverished) are likely to be those that cannot afford traditional healthcare, and may use herbal preparations to treat themselves.

Using medical examiner data from deaths occurring within the home is an effective way to collect unbiased reports of what kind of herbal medications are being used by residents in the state of New Mexico. Several studies have been conducted that show that medical examiner (ME) data bases can be successfully used in epidemiologic surveys.^{10,11,12} Although the ME database is not representative of all deaths in the state of New Mexico, it does contain demographic and medical information that is sometimes hard to collect in community studies.¹⁰ In fact, the New Mexico ME system has been used in the past to study the rates of poisoning deaths and deaths related to methadone overdose.^{11,12} New Mexico is unique, in that it has a centralized medical examiner system that catches a wide range of the deaths that occur in all regions of the state.¹¹

Methods

The ME office in New Mexico is called OMI, or the Office of the Medical Investigator. The OMI is authorized to investigate all deaths in New Mexico that are sudden, unexplained, suspicious, violent or unattended by a physician, with the exception of those that occur within certain tribal and federal jurisdictions

such as Indian reservations and military installations. However, the OMI is often consulted to investigate these deaths as well.^{11, 12} Eight board-certified forensic pathologists working at OMI's facility in Albuquerque, assisted by a network of 110 central office and field deputy medical investigators, certify cause and manner of death using data from scene investigations, toxicologic and microbiologic testing, and autopsies. OMI provides investigative services for approximately 5000 deaths per year, or about one-third of all deaths in New Mexico.

Reports of deaths occurring in a residence (house, apartment, trailer, hotel/motel room) between January 1, 2006 and June 30, 2006 were reviewed by the author to determine basic demographic information about the age, sex, living and employment situations of the deceased, as well as the kinds of medications and supplements that they used. A log is filled out by scene investigators, who were instructed to log all prescription and over the counter medications as well as any herbal medications that are found in the house. Relevant data were abstracted from electronic and hard copies of the files using a standardized abstraction sheet developed by the author.

Data were entered into an Excel spreadsheet and analyzed using SAS 9.1. Categorical variables (gender, ethnicity) were compared using Chi-square or Fisher exact tests, and continuous variables (age) were compared using t-tests or ANOVAs. P-values of 0.05 or less were considered significant. Populations where herbal supplements were identified at the scene of the death were compared to those who had no supplements present at the time of death,

using t-tests to compare mean ages, and chi-square analyses to determine associations between the presence of herbal supplements and categorical variables, such as gender, race/ethnicity, cause of death, and geographical location within the state.

Results

In the first half of 2006, there were 1112 home deaths, providing an adequate sample size to obtain an accurate look at herbal use in New Mexico. The majority of decedents included in this study were male (62%) and white non-Hispanic (66%). Women included in this study population were significantly older than the men ($p < 0.0001$), with a mean age of 68 years versus 62 years (Age distribution shown in Fig. 1). The majority of decedents were not married (54%), and not employed (61%). The majority of deaths were natural (76%), followed by accidental (13%).

The most common cause of death in this study was Atherosclerotic Cardiovascular Disease (30%), followed by drug intoxication (11.5%), gunshot wound of head (4.8%), Congestive Heart Failure (4.5%) and Chronic Obstructive Pulmonary Disease (4.1%).

Hypertension was the most commonly identified medical condition (29%), followed by cardiac (28%) and diabetes (17%). Only 16% of the decedents had no medical conditions mentioned in the investigation of their deaths. 33% had one, 25% had two, and 25% of decedents had three to seven medical conditions noted.

In keeping with hypertension being the most commonly found medical condition, anti-hypertensive medications were the most commonly found category of prescription/over-the-counter (OTC) medications (32%), followed by “other” (29%), narcotics (27%) and antidepressants (19%) (See Table 1). Twenty eight percent of decedents had no prescription/OTC drugs found at the scene of their death, while 12% of decedents had one prescription/OTC drug found at the time of their death, and 12% had two. Forty eight percent had three or more, with one person having 14.

Multivitamins were the most commonly found supplement, found at 5% of the death scenes included in this study. Next most commonly found were other types of supplements not matching any of the other categories (8%), Vitamin C (3%), B vitamins (3%), and calcium (3%) (Table 2). The majority of decedents (86%) had no supplements seen or recorded at their residence at the time of death. Seven percent had one, 2% had two, and 4.6% had three or more supplements found at the time of their death.

There was no statistically significant difference in gender among people having three or more supplements (51 decedents) present at the scene of death when compared to those having two or fewer (1061 people) ($p=0.48$). There was no statistically significant difference in racial/ethnic distribution among people having three or more supplements present at the scene of death when compared to those having two or fewer ($p=0.06$). There was no statistically significant difference in marital or employment status between those with three or more supplements and those with two or fewer ($p=0.08$ and $p=0.63$, respectively).

Decedents having three or more supplements present in their residence at the time of death were older than those with two or fewer, (mean age of 67.6 years versus 63.9 years), but the difference was not significant ($p=0.18$).

Decedents with three or more prescription/OTC drugs found at the death scene were 3.03 times more likely to have three or more supplements as well, compared to those with two or fewer prescription/OTC drugs found on scene ($p=0.0003$, 95% confidence interval=1.56-5.96).

Discussion

This is the first study that takes advantage of a medical examiner system to review the use of herbal medication, vitamin and other supplement use within a population. This presents useful information because it allows information to be gathered without barriers from language or from the bias of memory problems inherent in self-report surveys.

Supplements were found in the possession of many cross sections of the population. With no statistical difference found between gender, race, marital or employment status, it is clear that the use of herbal medications and other supplements is an issue that crosses all demographics. The population that was found to have herbals tended to be elderly, but this is not surprising, given that the entire population in this study had a mean age greater than 62. This is easily explained by the number of natural deaths that predominated this study, and which occurred at home.

Previous studies examined the use of at least one alternative therapy during the previous year, and showed a rate of 33.8% in 1990 and 42.1% in 1997.² This study also looked at other modalities than herbals, but showed a 12.1% use in 1997, with a 5.5% use of megavitamins. Another study on herbal remedy use among the elderly showed that

one quarter of Asian and Hispanic elders used herbal remedies and that 10% of Black and White elders used them.¹³ One Australian study in 2007 showed that 53.8% of a 1,296 peri- and post-menopausal woman sample had visited a CAM practitioner and/or used a CAM product during the last year, with 25.4% and 18.4% using Soy and Evening Primrose Oil, respectively.¹⁵

Although the results of this study demonstrate lower percentages of herbal use, this is likely due to the major limitation of the study, which is reliance on over one-hundred field investigators for data collection in the form of filling out medication logs in a thorough, uniform and reproducible manner on every residential death. This was the first time that investigators were required to record all herbal supplements and vitamins in addition to all prescription and OTC medications on every residential scene, regardless of the status of the case. The results showed an inconsistency in the practice of logging medications. After several written instructions were dispersed about the specific rules for data collection, some investigators were noted to have improved documentation techniques.

If this study were to be repeated, there would be benefit from some type of certification course that would create a more uniform and reproducible form of data collection. For example, reports of death could be examined as soon as they are submitted to determine if all information has been included, and investigators could be given timely feedback about the investigation and its completeness. Use of a simple statement, “no medications or supplements found on scene” would allow researchers to definitively discern whether or not medications were found on scene. With a greater uniformity and reliability of data collection being achieved, a study such as this, using

Medical Examiner scene investigations, is still a promising method of assessing the use of herbal medications and other supplements by the general population. Given that the majority of deaths investigated by medical examiners are natural and occur in residential settings, medical examiner's offices could be a very rich source of data for investigation of the prevalence of herbal supplements and over-the-counter medications.

The population included in this study was generally over the age of 65, which has been shown in other studies to be the segment of the population consuming a large portion of these products^{13, 14}. This is also a population that is susceptible to a variety of diseases, and therefore likely to be in possession of many prescription medications as well. Knowing that an older population is more likely to use herbals and supplements, as well as having an increased likelihood for using multiple prescription medications highlights the importance of continuing to look at the patterns of herbal and supplement use, and the possibility of interaction with prescription and OTC medications.

Given the results of the current study, it is difficult to determine the actual magnitude of the use of herbal medications and supplements in the state of New Mexico; the authors still suspect that the actual numbers may be higher than presented here. Further studies will need to be conducted to know for sure, and should be conducted due to the dangers of potential interactions with many herbal medications, including induction of CYP 450, coumarinic reactions, as well as those that are yet unknown to physicians and patients alike.

Figure 1

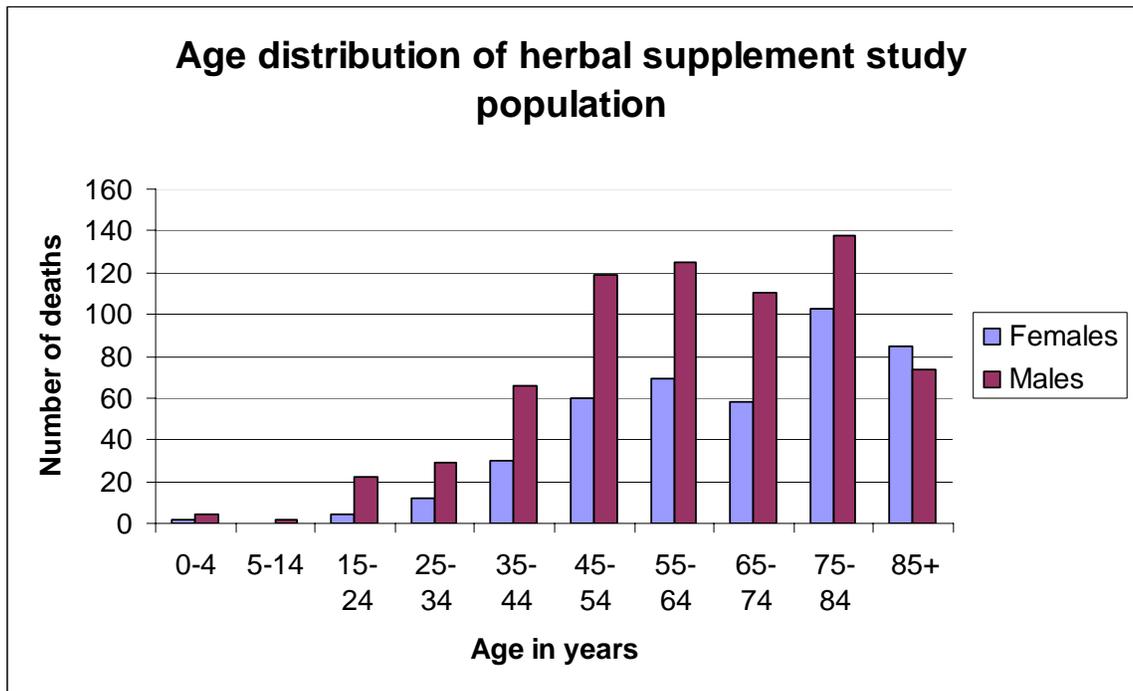


Figure 2

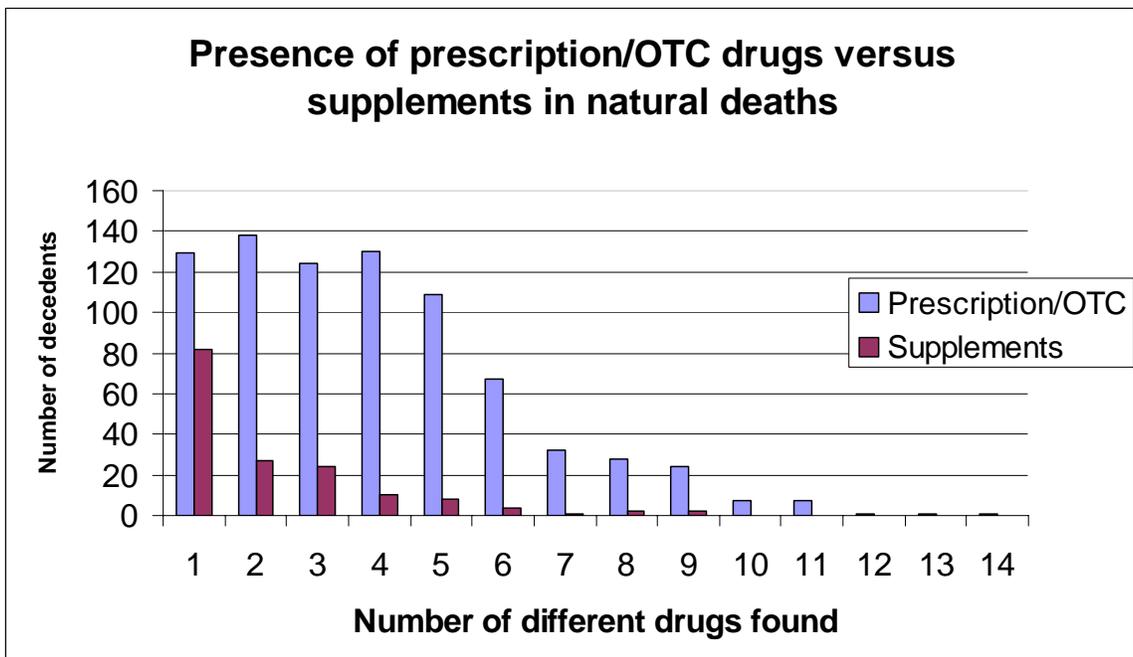


Table 1. Medications Found On Scene

Drug Category	N	%
Antiepileptics	90	8
Narcotics	305	27
Acid Blockers	159	14
Anti-Cholesterol	135	12
Bronchodilators	99	9
Steroids	59	5
Thyroid	77	7
Antidepressants	207	19
Antibiotics	134	12
Glycemic agents	122	11
Anxiolytics	205	18
Anticoagulants	78	7
Diuretics	192	17
Antihypertensives	356	32
Antipsychotics	79	7
OTC Meds	179	16
NSAIDS	82	7
Muscle relaxants	48	4
Antiemetics	61	5
Other	321	29
Prescription supplements	106	10
No meds	131	12
No meds listed	177	16

Table 2. Supplements Found On Scene		
Supplement	N	%
Multivitamins	56	5
Vitamin C	36	3
Vitamin A	4	0.4
Vitamin D	7	0.6
Vitamin E	17	2
Vitamin K	3	0.3
B vitamins	31	3
Calcium	30	3
Zinc	12	1
Iron	15	1
Thiamine	6	0.5
Folate	16	1
St. John's Wort	1	0.1
Echinacea	6	0.5
Ginseng	2	0.1
Garlic	5	0.5
Gingko	4	0.4
Glucosamine/Chondroitin	11	1
Saw palmetto	6	0.5
Other supplements	85	8
3 or more supplements	51	5

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