



Women who abuse prescription opioids: Findings from the Addiction Severity Index-Multimedia Version[®] Connect prescription opioid database

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ARTICLE INFO

Article history:

Received 26 January 2009

Received in revised form 22 March 2009

Accepted 23 March 2009

Keywords:

Gender

Opioids

Prescription opioids

Substance-related disorders

Surveillance

Overdose

ABSTRACT

Background: Evidence suggests gender differences in abuse of prescription opioids. This study aimed to describe characteristics of women who abuse prescription opioids in a treatment-seeking sample and to contrast gender differences among prescription opioid abusers.

Methods: Data collected November 2005 to April 2008 derived from the Addiction Severity Index Multimedia Version Connect (ASI-MV[®] Connect) database. Bivariate and multivariable logistic regression examined correlates of prescription opioid abuse stratified by gender.

Results: 29,906 assessments from 220 treatment centers were included, of which 12.8% ($N = 3821$) reported past month prescription opioid abuse. Women were more likely than men to report use of any prescription opioid (29.8% females vs. 21.1% males, $p < 0.001$) and abuse of any prescription opioid (15.4% females vs. 11.1% males, $p < 0.001$) in the past month. Route of administration and source of prescription opioids displayed gender-specific tendencies. Women-specific correlates of recent prescription opioid abuse were problem drinking, age < 54 , inhalant use, residence outside of West US Census region, and history of drug overdose. Men-specific correlates were age < 34 , currently living with their children, residence in the South and Midwest, hallucinogen use, and recent depression. Women prescription opioid abusers were less likely to report a pain problem although they were more likely to report medical problems than women who abused other drugs.

Conclusions: Gender-specific factors should be taken into account in efforts to screen and identify those at highest risk of prescription opioid abuse. Prevention and intervention efforts with a gender-specific approach are warranted.

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1. Introduction

Over the past few decades, the number and available potency of pharmaceutical prescription opioids has expanded dramatically (Volkow, 2008), equipping clinicians with a much needed, wider array of analgesics in the treatment of pain. However, because these same key drugs are potentially abuseable, these advances have been subjected to careful scrutiny prior to their approval for therapeutic use and, even after their approval, as the objects of potential diversion and abuse. Estimates from the U.S. National Survey on Drug Use among Households (NSDUH) from 1990 to 2006, reflect trends of increasing self-reported recent abuse of prescription opioids (Cicero et al., 2005; Dasgupta et al., 2006; Galaif et al., 2001; Gilson et al., 2004; SAMHSA, 2006; Zacny et al., 2003). During the same period, the number of prescription opioid-involved deaths

increased (Paulozzi et al., 2006), with some areas of the country now reporting more than 90% of unintentional poisoning deaths attributable to prescription opioids (Hall et al., 2008). Many explanations for this upsurge in prescription opioid abuse exist including increases in prescribing practices (Wisniewski et al., 2008), expansion of medical use of opioids in primary care (Reid et al., 2002), the introduction of multiple potent and modified-release formulations (Goodman and Glassman, 2005), the increase in prescribing of methadone for outpatient pain management (Nicholson, 2007), and limited opioid substitution treatment options (Brands et al., 2004; Hall et al., 2008).

Women represent a large and growing population of prescription opioid abusers (Cicero et al., 2008; SAMHSA, 2006; Tetrault et al., 2008). Unlike for heroin, an equal or greater proportion of women appear to abuse prescription opioids (Kelly et al., 2008; Simoni-Wastila et al., 2004). It is well-established that various gender differences exist, including those rooted in biology (Lynch et al., 2002), which may influence the abuse of alcohol and illicit drugs. For example, women drug abusers are more likely than men to report psychiatric problems (Lin et al., 2004; Milani et al., 2004)

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and histories of physical, emotional, and/or sexual abuse (Galaif et al., 2001; Gentilello et al., 2000) which put them at greater risk of abuse of drugs. Studies conducted outside of the United States suggest worrying increases in abuse of prescription opioids among women who obtained these drugs through their own prescriptions (Anon., 2005; Lloyd, 2008). Women tend to use and to be prescribed abuseable medications more often than men (Isacson and Bingefors, 2002; Simoni-Wastila, 1998) and are more likely to report prescription opioids as their primary drug of abuse (Office of Applied Statistics, 2001, 2005). Despite these trends, there have been few efforts to explore the nature of prescription opioid abuse among women or to understand the special considerations for diagnosis, prevention, drug-related risks and treatment of women who abuse prescription opioids in the United States.

This study examined data from patients entering substance abuse treatment to explore the role of gender in abuse of prescription opioids. Specifically, there were two aims: first, to describe the characteristics of women as compared to men who abuse prescription opioids in a treatment-seeking sample and second, to contrast gender differences among prescription opioid abusers in order to identify gender-specific correlates of abuse.

2. Methods

2.1. Data source

Participants for this study comprised of clients 18 years and older attending substance abuse treatment centers across the United States who completed the Addiction Severity Index-Multimedia Version® (ASI-MV®) Connect (Butler et al., 2008) (see description below) as part of their treatment experience. The ASI-MV® Connect is a commercial product, purchased by treatment facilities for efficient and cost-effective patient evaluation and treatment planning purposes and is used as part of the standard clinical intake. Treatment centers in the ASI-MV® Connect network include primarily inpatient/residential units, outpatient non-methadone sites, and methadone maintenance programs, but respondents also may have completed the ASI-MV® Connect as part of their experience in drug court, probation/parole, TANF (Temporary Assistance for Needy Families) programs, or DWI/DUI (Driving While Intoxicated/Driving Under the Influence) programs. Thus, the data presented here are collected as part of ongoing clinical care and not as part of a study. Patient level data are made HIPAA (Health Insurance Portability and Accountability Act) compliant, de-identified, and uploaded to a server at Inflexion, Inc. The research reported here is exempt from IRB policy since it uses de-identified patient data collected under a Business Associate Agreement and Limited Data Set Use Agreement with participating treatment facilities around the country under conditions specified under the Code of Federal Regulations.

The ASI-MV® Connect is a component of the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO™) (Butler et al., 2008). NAVIPPRO™ is a comprehensive risk management system for prescription opioids and other Schedule II and III therapeutic agents. The Food and Drug Administration (FDA) developed guidelines (DHHS, 2008) for pharmaceutical companies that make or submit new drug applications (NDAs) for substances with potential for abuse or addiction. These guidelines call for the creation of Risk Evaluation and Mitigation Strategy plans (called REMS), previously known as risk minimization action plans, or RiskMAPs, that include post-marketing surveillance to monitor indicators that might suggest the occurrence of adverse events, such as an emerging trend of abuse. NAVIPPRO™ was developed to provide post-marketing surveillance, signal detection, signal verification, and targeted prevention and intervention strategies. ASI-MV® Connect data are used as part of NAVIPPRO™ to monitor prescription abuse reported by individuals entering substance abuse treatment (see Butler et al., 2008), alongside other data sources including publicly available datasets, such as the National Survey on Drug Use & Health (NSDUH), the Treatment Episode Data Set (TEDS), the FDA Adverse Event Reporting System (FDA-AERS), the Drug Abuse Warning Network (DAWN Live!), and the American Association of Poison Control Centers' (AAPCC) New Core System database (NCSBeta) and a proprietary database of Internet posts called Web Informed Services (WIS). These data are also examined, as the ASI-MV® Connect data are here, to increase our understanding of abuse patterns and trends in the United States.

2.2. Measures: ASI-MV® Connect

The ASI-MV® Connect is a continuous, real-time data stream that collects data on substances used and abused by adult clients (18 years or older) entering a substance abuse treatment. The ASI-MV® is a modified version of the Addiction Severity Index (ASI); a standard intake assessment designed for use upon treatment admission with demonstrated reliability and validity (Hendricks et al., 1989). The ASI assesses severity of addiction and the need for treatment (McLellan et al., 1992; McLellan et al.,

1980) by measuring patients' medical, employment, drug, legal, family and social relationships, and psychiatric problems. The ASI-MV® is a computer-administered version of the traditional ASI interview that is conducted by on-screen interviewers who present the questionnaire items according to a tree-logic that asks follow up questions only when appropriate, simulating a live interviewer. ASI questions are presented in both text and audio to address literacy limitations. An upgraded version of the ASI-MV®, called the ASI-MV® Connect, collects product-specific, geographically sensitive information about prescription opioids in addition to questions about the client's route(s) of administration (oral, smoking, snorting, injecting), source of drug, presence of pain and pain treatment. The ASI-MV® Connect is web-enabled so that de-identified client information is uploaded to a central server and is, therefore, available immediately for review and analysis.

Prescription opioid use was operationalized as self-reported past 30-day use of any prescription opioid while prescription opioid abuse was operationalized as self-reported past 30-day use of any prescription opioid "in a way not prescribed by your doctor, that is, taking it for the way it makes you feel and not for pain relief". The focus of this analysis is on abuse of prescription opioids, however, we present limited data on self-reported use of prescription opioids to reflect the high prevalence of any use (e.g., for medical purposes, for psycho-physiologic effects, etc.) in the population. The ASI-MV® Connect currently tracks 64 branded and generic prescription opioids. In addition to prescription drug variables, the ASI-MV® obtains self-report of a number of medical, psychosocial and psychiatric variables (McLellan et al., 1980, 1992). Relevant variables, considered for this analysis, included socio-demographics (age, race/ethnicity, gender, employment and educational status defined as < and ≥12 years education, currently living with their children, currently living with anyone who uses non-prescription drugs, family conflicts, incarceration history, patient's 3-digit residential ZIP code, Census region of respondent's residence), current illicit drug use by substance, duration of any illicit drug use, history of overdose, concurrent medical and psychiatric problems/symptoms, presence of chronic pain, treatment for pain, current receipt of psychiatric medications, and product-specific source and route of administration of prescription opioids tracked by the ASI-MV® Connect. Drugs of abuse that are monitored, in addition to prescription opioids, include alcohol, heroin, methadone maintenance, barbiturates, sedatives/hypnotics/tranquilizers (grouped together), cocaine, amphetamines, cannabis, hallucinogens, and inhalants (all inhalants grouped together). Medical and psychiatric problems were self-reported symptoms and problems and not diagnosed conditions. The medical problems variable was dichotomized as yes/no if the respondent reported experiencing physical or medical problems (e.g., illness, pains, discomfort, disability, or a severe cold or flu but not including drug or alcohol symptoms or withdrawal) for more than one day in the past thirty. The psychiatric problems inquired about in the ASI-MV® Connect and analysed for this study included past 30-day experience of depression, anxiety, hallucinations, violence (i.e., "trouble controlling violent behavior including episodes of rage, or violence"), suicidal thoughts, and suicide attempts. To clarify, questions asking about self-reported pain problems, medical problems, and being prescribed pain medications were asked of all respondents and receipt of these questions did not depend on responses to earlier questions. Thus, it was possible to report being prescribed pain medications but to not currently be experiencing a medical or pain problem.

2.3. Study sample

The study sample consisted of 29,906 assessments from people entering substance abuse treatment from November 2005 through March 2008, of whom 3821 (12.8%) self-reported abuse of prescription opioids in the past month. Assessments were conducted in 220 treatment centers representing 175 unique site 5-digit zip codes and 362 unique client 3-digit zip codes. The mean age of the sample was 34.9 years (S.D. = 11.6, range 13–87); males represented 61% of the sample. Approximately half (47%) of the sample was non-white, with 8% African-American, 31% Hispanic/Latino, 1% Asian, 6% Native American, and 1% other ethnicity.

2.4. Data analysis

The first goal of the study aimed to describe the characteristics of women, as compared to men, who abused prescription opioids. Descriptive and bivariate analyses (i.e., χ^2 tests, *t*-tests, or other appropriate non-parametric tests) were conducted among prescription opioid abusers only (i.e., patients endorsing non-medical use of any prescription opioid in the past 30 days; $N=3821$). To accomplish the second aim of identifying correlates of prescription opioid abuse, we performed multivariable logistic regression analyses using the full dataset ($N=29,906$), stratified by gender. Since evidence suggests that gender may be an important moderator of prescription opioid abuse (Tetrault et al., 2008) and women drug abusers differ from men who abuse drugs, we performed stratification rather than including a series of model interaction terms. Using bivariate analysis and a cutoff of $p < 0.15$, the modeling approach consisted of first screening for possible correlates, selected for testing based on the literature (Becker et al., 2008; Cicero et al., 2008; Grau et al., 2007; Tetrault et al., 2008). This screening was done separately for men and women. We then incorporated candidate variables into gender-specific multivariable models in a non-automated backward stepwise fashion, testing for changes in statistical significance, improved model fit, and evidence of confounding. The final

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