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Primary care patient characteristics associated with completion of 6-month buprenorphine treatment

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HIGHLIGHTS

- Primary care patients with opioid addiction received buprenorphine for 6 months.
- We assessed characteristics associated with completion of buprenorphine treatment.
- Counseling attendance was associated with buprenorphine treatment retention.
- Past physical injury was associated with 6-month treatment completion.
- Analgesia due to buprenorphine may increase the likelihood of treatment retention.

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ABSTRACT

Background: Opioid addiction is prevalent in the United States. Detoxification followed by behavioral counseling (abstinence-only approach) leads to relapse to opioids in most patients. An alternative approach is substitution therapy with the partial opioid receptor agonist buprenorphine, which is used for opioid maintenance in the primary care setting. This study investigated the patient characteristics associated with completion of 6-month buprenorphine/naloxone treatment in an ambulatory primary care office.
Methods: A retrospective chart review of 356 patients who received buprenorphine for treatment of opioid addiction was conducted. Patient characteristics were compared among completers and non-completers of 6-month buprenorphine treatment.
Results: Of the 356 patients, 127 (35.7%) completed 6-month buprenorphine treatment. Completion of treatment was associated with counseling attendance and having had a past injury.
Conclusions: Future research needs to investigate the factors associated with counseling that influenced this improved outcome. Patients with a past injury might suffer from chronic pain, suggesting that buprenorphine might produce analgesia in addition to improving addiction outcome in these patients, rendering them more likely to complete 6-month buprenorphine treatment. Further research is required to test this hypothesis. Combination of behavioral and medical treatment needs to be investigated for primary care patients with opioid addiction and chronic pain.

1. Introduction

By all metrics, prescription drug dependence is an epidemic in the United States. According to the Centers for Disease Control and Prevention (CDC), the number of unintentional deaths by overdose with opioid analgesics increased from approximately 3000 in 1999 to approximately 11,000 in 2007. In 2007, the number of unintentional deaths by overdose with opioid analgesics was 1.93 times the number of unintentional deaths by overdose with cocaine and 5.38 times the number involving heroin (National Center of Injury Prevention & Control, 2011). Across the United States, 14,800 deaths were the result of opioid pain relievers in 2008 (Paulozzi, Jones, Mack, & Rudd, 2011). Nationwide, overdose by prescription opioids was the second highest cause of accidental death following motor vehicle accidents, and in some states it is the highest (Kochanek, Xu, Murphy, Miniño, & Kung, 2011). According to the Treatment Episode Data Set (TEDS), admissions for non-heroin opiate use increased about six-fold from 22,509 in 1999 to 138,742 in 2009 (SAMSHA, 2011).

In the past, the standard of care for this growing problem has been detoxification followed by behavioral counseling (i.e. abstinence), which often results in relapse. An alternative to behavioral treatment alone is buprenorphine, which has been approved by the U.S. Food and Drug Administration (FDA) for office-based opioid addiction maintenance treatment (SAMSHA, 2005). Fudala et al. (2003) found that

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patients receiving buprenorphine/naloxone treatment had a greater proportion of urine samples that were negative for opiates and reported less opioid craving than patients receiving a placebo. Buprenorphine is a partial agonist of the μ-opioid receptor and κ antagonist. The partial agonist properties of buprenorphine produce a "ceiling effect," which grants buprenorphine a lower abuse potential than full agonists such as methadone and heroin, resulting in a safety profile superior to other agonists (Johnson, Strain, & Amass, 2003). Buprenorphine has been widely studied for its use in the office-based treatment of opioid addiction (Barry et al., 2009; Fiellin et al., 2008; Fudala et al., 2003; Moore et al., 2007; Soeffing, Martin, Fingerhood, Jasinski, & Rastegar, 2009).

Completion rates of buprenorphine treatment vary by population and length of treatment. Kakko, Svanborg, Kreek, and Heilig (2003) showed that 1-year buprenorphine treatment retention was 75% compared to 0% for detoxification followed by behavioral counseling treatment. Fiellin et al. (2008) found that 32% of opioid-dependent patients completed 6 months of buprenorphine treatment in a primary care office-based setting. Of those, 24% remained in treatment for 3 years and 6% remained in buprenorphine/naloxone treatment for 5 years. According to an earlier study, Fiellin et al. (2006) showed that 6-month buprenorphine treatment retention was 35% for all patients regardless of dispensing schedules and type of counseling. In a study by Moore et al. (2007), the approximate 6-month buprenorphine/naloxone treatment retention rate was 36% across all patients in an office-based setting. According to Soeffing et al. (2009), 1-year retention in buprenorphine treatment was 56.9% in a primary care setting. Individuals dependent on prescription opioids were more likely to remain in treatment, remained in treatment longer, and had a higher percent of opioid-negative urine than those who exclusively or episodically used heroin. Barry et al. (2009) showed that patients are satisfied with primary care office-based buprenorphine/naloxone treatment.

Patient characteristics associated with completion of buprenorphine treatment for opioid-dependence have been poly-substance abuse, prescription opioid abuse as opposed to heroin use, female gender, older age, White race, being employed, self-maintaining with illicit buprenorphine, counseling attendance, AA attendance, less substance use, sedative dependence, and receiving psychiatric medication (Alford et al., 2011; Haddad, Zelenev, & Altice, 2013; Parran et al., 2010; Schottenfeld, Pakes, & Kosten, 1998; Stein, Cioe, & Friedmann, 2005). In one study by Soeffing et al. (2009), 12-month buprenorphine treatment retention was associated with poly-substance use (cocaine and alcohol) and assignment to an attending or resident physician compared to a nurse practitioner in a primary care office setting. Treatment success as defined by opioid-negative urines was associated with prescription opioid use rather than heroin use. In contrast to Soeffing et al. (2009), cocaine use has been a predictor of non-completion of buprenorphine treatment (Alford et al., 2011; Neumann et al., 2013; Sullivan et al., 2009). Previous research suggests that higher educational level is associated with completion of methadone maintenance treatment (Ren et al., 2013).

The present study was a secondary data analysis of a quality assurance study investigating the primary care patient characteristics of completion of 6-month buprenorphine treatment in a real world setting. Many of the studies mentioned above excluded patients due to a psychiatric diagnosis and use of drugs other than opioids. However, we included these patients to strengthen the external validity of the study. In addition to the variables predictive of treatment completion addressed above, we hypothesized that the following primary care patient characteristics predict treatment completion: no polysubstance abuse problem, no psychiatric disorder, not being single, no family history of opiate or alcohol addiction, and no past history of emotional trauma.

2. Material and methods

We used a de-identified data set from treatment center records. The institutional review board at the University at Buffalo reviewed the study protocol and approved it as an exempt study.

2.1. Participants

The study population consisted of 553 treatment-seeking individuals, aged 16 to 70, who received outpatient buprenorphine treatment at an ambulatory primary care setting and were either discharged from or left the program between January 2008 and May 2012. As the hospital closed in summer 2012 we attempted to review all medical charts of the ambulatory clinic within a 2-week period. However, due to the time constraint of 2 weeks, of the 553 medical charts, 356 reviews were completed. Therefore, no specific procedures and exclusion criteria for participant selection was applied. Patients had a diagnosis of opioid dependence that was based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) for opioid dependence (American Psychiatric Association, 2000).

2.2. Setting

The study was conducted in an ambulatory primary care office that was staffed with 3 part-time primary care physicians who provided addiction services, 1 receptionist, and 1 chemical dependency counselor who served as clinic treatment coordinator. This clinic was located within a hospital that provided outpatient primary care and substance abuse counseling services as well as medically managed detoxification and substance abuse rehabilitation inpatient services. The ambulatory primary care clinic required the patients to have health insurance and the means to purchase the medications.

Buprenorphine treatment did not have a predetermined fixed duration, but we used 6 months as a cut-off because it is an indicator as to whether a patient is stabilized. Patients were prescribed the combination buprenorphine–naloxone formulation (Suboxone®). Buprenorphine doses ranged from 4 to 32 mg per day, with most patients receiving 12 to 16 mg. Patients were induced at the office with the induction medication dispensed from the pharmacy that was available on site. For induction, patients were given an initial dose of 4 mg of buprenorphine and were observed. If needed, an additional dose of 2 mg of buprenorphine was administered after 2–4 hours to control the symptoms and signs of opioid withdrawal. The participants were sent home with a prescription to take buprenorphine/naloxone at gradually increasing doses (8/2 mg on day 1, 12/3 mg on day 2, and 16/4 mg on day 3 and thereafter). A follow-up appointment was scheduled within 5 to10 days of initial treatment. All participants were advised not to drink any alcoholic beverages, not to obtain prescriptions from other physicians for any controlled substances, not to return to taking any of their previously prescribed opioids, and not to use any illicit drugs. Participants were required to engage in chemical dependency counseling, preferably on-site at the substance abuse counseling services of the hospital. However, some patients were restrained by insurances to use other locations, and other patients preferred counseling services closer to their home. Participants were also encouraged to attend meetings of self-help programs (e.g., Narcotics Anonymous). After stabilization, patients were seen for monthly follow-up appointments and were required to provide urine samples at every visit. Possible diversion was monitored by counting left-over pills, requiring participants to have a lockbox for their medication, and completing a daily treatment diary. Patients who experienced pain, complications with the medication, or continued to use illicit opioids or other substances were seen more frequently, usually every two weeks. Once stabilized, patients returned to monthly visits.

2.3. Data collection and management

Treatment professionals at the program collected information about the participants on paper forms of the medical chart at each visit. Later, data were abstracted anonymously from the medical record onto an electronic database by the treatment center personnel. When entering the data in the electronic database the data were coded. This de-