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Prescription Opioid Taper Support for Outpatients With Chronic Pain: A Randomized Controlled Trial

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Abstract: **Patients receiving long-term opioid therapy for chronic pain and interested in tapering their opioid dose were randomly assigned to a 22-week taper support intervention (psychiatric consultation, opioid dose tapering, and 18 weekly meetings with a physician assistant to explore motivation for tapering and learn pain self-management skills) or usual care (N = 35). Assessments were conducted at baseline and 22 and 34 weeks after randomization. Using an intention to treat approach, we constructed linear regression models to compare groups at each follow-up. At 22 weeks, adjusted mean daily morphine-equivalent opioid dose in the past week (primary outcome) was lower in the taper support group, but this difference was not statistically significant (adjusted mean difference = −42.9 mg; 95% confidence interval, −92.42 to 6.62; *P* = .09). Pain severity ratings (0–10 numeric rating scale) decreased in both groups at 22 weeks, with no significant difference between groups (adjusted mean difference = −.68; 95% confidence interval, −2.01 to .64; *P* = .30). The taper support group improved significantly more than the usual care group in self-reported pain interference, pain self-efficacy, and prescription opioid problems at 22 weeks (all *P*-values < .05). This taper support intervention is feasible and shows promise in reducing opioid dose while not increasing pain severity or interference.**

Perspective: ***In a pilot randomized trial comparing a prescription opioid taper support intervention to usual care, lower opioid doses and pain severity ratings were observed at 22 weeks in both groups. The groups did not differ significantly at 22 weeks in opioid dose or pain severity, but the taper support group improved significantly more in pain interference, pain self-efficacy, and perceived opioid problems. These results support the feasibility and promise of this opioid taper support intervention.***

Key words: *Chronic opioid therapy, opioid dose taper, pain intensity, pain interference, pain self-management.*

The number of opioid prescriptions written annually in the United States now approximates the number of adults in the U.S. population. The percent of Medicare Part D recipients receiving opioid prescriptions for more than 90 days in a year increased from 4.6% in 2007 to 7.4% in 2012, with large variation among states, suggesting a lack of consensus about the indications for long-term opioid therapy (LtOT). The Medicare patients more likely to have prolonged use were characterized by older age, female gender, white race, low income, living in a lower-education area, and comorbidity of drug abuse, rheumatoid arthritis, or depression.[17] These populations are also at high risk for opioid adverse events such as overdose and abuse.[20] In 2011, half of all veterans with chronic noncancer pain (CNCP) received an opioid prescription during the year. More than half (57%) of these veterans received at least a 90-day supply of opioids and 10% received at least a 350-day supply. The median daily dose was 21 mg morphine-equivalent dose (MED), with 4.5% receiving more than 120 mg MED.[9]

Exposure to prescription opioids increases the risks for opioid abuse, overdose, and other adverse events in a

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dose- and duration-dependent manner.[11,19] There were almost 19,000 overdose deaths in the United States associated with prescription opioids in 2014.[3] These now exceed the number of deaths caused by motor vehicle accidents in the United States. In 2013, prescription opioids were also involved in more deaths than were all illicit drugs combined.[5] The prescribing of opioids for chronic pain also appears to contribute to the nonmedical use of opioids. Data from the National Survey of Drug Use and Health suggest that prescribers are, directly or indirectly, the source of most misused opioids.[28]

It is possible that decreasing doses of opioids prescribed to patients with chronic pain may reduce these risks to patients and the general population.[23] Opioid tapering after years of therapy may be difficult for the patient and is feared by many patients. It is possible that opioid taper may be accomplished without significant worsening of pain, mood, and function, according to data concerning opioid taper within multidisciplinary pain rehabilitation programs.[30] However, no protocol for taper of LtOT among outpatients treated for chronic pain has been tested. The effects of tapering LtOT dose on pain, function, and mood remain unknown. This information would be helpful to patients contemplating opioid taper and their physicians, and possibly also in understanding the value of LtOT for CNCP because of the absence of randomized controlled trials (RCTs) of LtOT.

The objectives of this pilot study were to 1) show the feasibility of a prescription opioid taper support intervention for patients receiving moderate- or higher-dose LtOT for CNCP who had no evidence of current substance abuse, and 2) conduct a pilot RCT to evaluate the effectiveness of this intervention. We hypothesized that patients randomized to the opioid taper support intervention, compared with patients randomized to usual opioid prescribing care, would have lower opioid doses (primary outcome) at 22 weeks (primary end point and end of intervention period) and 34 weeks after randomization. We explored effects of the intervention on opioid misuse, pain severity, pain-related activity interference, pain self-efficacy, depressive symptoms, opioid-related problems, and opioid-related concerns.

Methods

Study Design, Participants, and Setting

This nonblinded RCT was conducted at the University of Washington (UW) Medicine Center for Pain Relief in Seattle, Washington. The study was approved by the UW institutional review board and overseen by an independent data and safety monitoring committee. All participants provided written informed consent. Study enrollment occurred from May 2013 to September 2015. Fig 1 shows participant flow through the study.

Study participants were recruited through clinician referrals and clinic advertisements at the UW Medicine Center for Pain Relief and via referrals from other UW medicine specialty and primary care clinics and other Seattle pain clinics. Recruitment was initially limited to the Center for Pain Relief, but was expanded to other pain clinics and primary care clinics because of slow enrollment. Study inclusion criteria at study initiation were CNCP, defined as pain on more than half of the days in the past 6 months; use of opioid medication on more than half of the previous 90 days; willingness to taper opioid dose by at least 50% (or to 120 mg MED, whichever was less); daily MED ≥50 mg; recent urine drug test with no aberrancy; and future visits scheduled at the Center for Pain Relief. After enrollment began, the requirements for a 50% (or 120 mg) taper goal, recent urine drug test, and future visits scheduled at the Center for Pain Relief were removed and the required opioid dose at study entry was lowered to ≥25 mg MED to increase enrollment.

Patient exclusion criteria at the time of study entry were: 1) currently receiving treatment for cancer (other than nonmelanoma skin cancer), 2) medical comorbidity with life expectancy <1 year or otherwise considered medically unstable (as judged by the referring physician), 3) use of parenteral, transdermal, or transmucosal opioids or naltrexone within the previous month, 4) currently residing in a skilled nursing or long-term care facility, 5) currently using any implanted device for pain control (eg, intrathecal pump, spinal cord stimulator, peripheral nerve stimulator), 6) surgery within the previous month or planned during the next 6 months, 7) report of suicide attempt or psychiatric hospitalization in the past 10 years or current suicidal ideation with specific plan or intent, 8) significant cognitive impairment, assessed using the 6-item screener,[4] 9) report of psychotic symptoms on the Modified MINI International Neuropsychiatric Interview,[27] and 10) report of current abuse of substances other than nicotine or marijuana according to the National Institute on Drug Abuse Alcohol, Smoking, and Substance Involvement Screening Test[12] (marijuana was allowed because it is legal under Washington state law). The exclusion for psychiatric hospitalizations within the past 10 years was changed to within the past year after study enrollment began to increase enrollment. Patients agreed not to initiate buprenorphine treatment while enrolled in the study. All other concurrent pain treatment was allowed.

Procedures

After clinician or self-referral to the study, potential participants were screened via telephone. Patients who were provisionally eligible and interested in study participation then completed an in-person screening visit with the study physician assistant (PA). At that visit, potential participants were shown a 14-minute video of interviews with patients who had successfully tapered off opioids concerning what they had gained by this. Patients also provided demographic information and rated their expectations of the intervention. Patients who met all study inclusion criteria and remained interested in participating in the study then provided written informed consent and were enrolled. All measures used to assess outcomes were administered by research staff via telephone at baseline (after the screening visit and before