A Complex Pain Patient who is Opioid Dependent

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49-year-old white woman is a disabled registered nurse. She has a complicated history of chronic back, neck, and extremity pain from multiple traumas. Her diagnoses have included bipolar disorder, attention deficit hyperactivity disorder (ADHD), and post-traumatic stress disorder (PTSD). She has untreated hepatitis C, and she is on continuous positive airway pressure (CPAP) therapy for sleep apnea. She was recently hospitalized for desquamative interstitial pneumonia (DIP), for which she takes 50 mg of prednisone daily. She has developed Cushing-like complications,

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and she is opioid-dependent for which she is being treated medically with methadone 40 mg/day. The patient has a history of chemical dependence. She has abused pain pills as well as heroin. She has participated in a methadone clinic where she received daily doses of 150 mg/day. She has abused stimulants including cocaine, and she currently is tobacco dependent.

As the patient's primary care provider and addiction specialist, I referred her to Dr. X, a respected colleague who is a seasoned rehabilitative medicine specialist and well qualified in

pain management. I generally find Dr. X compassionate and savvy in dealing with patients with co-morbid mental illness. After my routine follow-up of the patient, I copied Dr. X on the following patient progress notes:

"We reviewed the lab reports. Creatinine clearance is 104 which is well within normal limits. Her trough level of methadone is 188 which is less than what it should be for someone who is opioid dependent. I hope this information is helpful to Dr. X.

"To manage opioid dependence one seeks trough levels in the range of 200 or more. This patient's levels are particularly low, since she is taking both fluoxetine and cimetidine. Both of these substances possibly delay the metabolism of methadone. Hence, her dose of methadone is likely inadequate to effectively manage her disease and her pain. In addition, given her other medical conditions, it is my opinion, as a result of her opioid dependence being under-treated, that there are serious implications, even more than for the average opioid-dependent patient."

After receiving a copy of my progress notes, Dr. X called quite upset that I would put her at risk legally by saying what I said in the progress note and since I cc'd a copy to the pulmonary physician. Dr. X was upset that her opioid prescribing was being called "publically" into question. She even threatened to stop seeing the patient if I continued to write such progress notes. Furthermore, Dr. X explained the dose of methadone had been lowered because the patient was doing so much better. The patient was not expressing craving, her mood was better, and she was not coming across as she had in the past with "addictive behavior." Dr. X reported the patient had even expressed a desire to lower her dose.

In December 2011, the patient was receiving methadone 80 mg/day and reported an Activity and Pain (A & P) score of 29/100 (based on an in-house questionnaire derived from the Wisconsin Brief Pain Inventory). A score of 100 reflects total disability with the patient reporting the worst possible pain. In our experience, pain levels in the 20-30 range reflect successful chronic pain management. In June 2012, the patient's dose of methadone was 40 mg/day, and she reported an A & P score of 52. This escalation from 29 to 52 over six months reflects an 80% increase in pain.

One cannot be entirely confident in explaining sudden increases in pain and disability in complex pain patients, particularly in those without clear and objective evidence for acute nociception. Nonetheless, the decrease in this patient's methadone dose from 80 mg to 40 mg/day probably resulted in significant clinical effects. Furthermore, there were arguably no objective nociceptive reasons to explain the significant change in the pain score. These

circumstances, along with the low serum trough level of methadone (189 ng/ml, 12 hours after last dose) prompted me to write my colleague and provide my opinion as to inadequate methadone dosing.

Background

In January 2012, the state of Washington initiated laws that oblige prescribers to refer patients to designated pain specialists for a consultation if daily prescribed opioids surpass a morphine equivalent dose (MED) of 120 mg. Even when referred to tertiary care pain centers, patients who are opioid-dependent are commonly being advised that they need to lower their doses of opioids because "there is no reason for them to be on this high a dose of opioids." This advice is given despite solid evidence that opioiddependent patients require larger daily doses of opioids for proper management and prognosis.

The guidelines governing entrance into methadone maintenance treatment remain very strict and far beyond

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the establishment of a DSM-IV diagnosis of opiate addiction. The requirements for admission include multiple daily self-administrations of heroin or any short-acting opiate for one year or more (1).

For patients receiving methadone maintenance treatment, adequate doses are generally considered to be between 80 and 150 mg per day, resulting in therapeutic trough levels in the range of 250 to 400 ng/ml (2).

While relatively common in Europe, the appropriateness of offering opioid-agonist therapy in an office-based setting is sometimes questioned in the United States. In accordance with US guidelines, federal requirements stipulate only that physicians who offer office-based treatment refer the patient back to the original methadone clinic or another methadone clinic from which the referral has been arranged if any significant problems ensue (3).

There are no restrictions on the use of methadone for pain, even in the context of addiction. The US Drug Enforcement Agency (DEA) does not restrict DEA-registered opioid prescribing for justifiable medical purposes except for opioid-dependence maintenance. The exceptions to the opioid treatment restriction are for patients who

are or have been associated with a methadone clinic, as stated above, or are under the care of a physician with a buprenorphine waiver. One study reported success in office-based induction into methadone maintenance treatment (4).

It is well accepted, and it makes sense, that pain management is compromised by inadequately treated chemical dependencies. This particular case is exemplary.

Discussion

The confidence that clinicians have about prescribing opioids for pain may become problematic when patients are opioid-dependent. These patients can be expected to behave in ways that best preserve a relationship with their prescriber. Indeed, "smiling depression" is quite common in these patients. This is now especially true in the state of Washington where patients, even those with financial means, can have immense difficulty in finding a provider to prescribe them adequate opioids for complex chronic

> pain. The shortage is particularly acute in the context of a history of opioid or other chemical dependencies. Hence, these patients may smile and say thank you to their

doctor even when they know a dose reduction is harmful. They understandably fear being entirely cut off from their medicines.

Patients who are opioid-dependent and cut off from agonist therapy experience significant mortality within the first year (5-8). Along with the long-term recognized significant morbidity associated with complex chronic pain, the consequences of not providing adequate and necessary medical care to these patients with co-morbid conditions is devastating.

In diabetes management, physicians do not simply believe what the patient tells them or the results of a cursory exam. Physicians generally do not depend on the standard history and exam to determine the dose of insulin a diabetic patient needs. When a diabetic patient has co-morbid conditions, such as infections or circulatory problems, physicians routinely are concerned about adequate diabetic control. Physicians obtain fasting blood samples and measure long-term control with glycosylated hemoglobin levels. In contrast, physicians managing a complex pain patient seem satisfied to depend on the patient's reports and a cursory clinical exam. They do not recognize that

inadequate treatment of opioid dependence can have serious health and social consequences. With opioiddependence, as with diabetes, appropriate laboratory and behavioral testing is often indicated and treatment goals should be based on what current literature supports as "adequate treatment."

Clinicians can never be sure whether an opioid-dependent patient will respond best to 40, 60, 90, or 150 mg/day of methadone. Indeed, the therapeutic dose appears to have a bell-shaped distribution with a tail to the right and a mean around 85 to 90 mg/day. If trough levels are less than therapeutic levels and a patient is symptomatic with pain scores clearly in the disabling range, the risks from higher doses of methadone are relatively minor compared to the established benefits of better overall disease management. Any good physician typically weighs these decisions regarding the risks and benefits of a prescribed medicine.

The Washington State Experiment

Issues relating to the new legislation in the state of Washington were reported in The Pain Practitioner (Spring 2012). Access to effective medical care for those who have complex pain and chemical dependencies is highly limited. Our state's licensed chemical dependency services have very limited interaction with the primary care community, let alone specialists. In Washington it is common for an addiction medicine specialist to never get a referral from a chemical dependency agency despite the overwhelming evidence supporting medical care in addictive disorders. The experiment in Washington regarding mandating limits on opioid prescribing is likely to be successful in reducing the incidence of opioid-related overdose deaths. Perhaps, however, it is tantamount to closing hospitals or avoiding surgeries to avoid complications thereof?

Our state's Medicaid program is particularly concerned because 50% of the overdose deaths recorded were among their clients. It maintains a list of "high prescribers" with the implication that these are "problem" physicians. There are sound and professionally acceptable reasons to prescribe more methadone than usual for pain. When patients on chronic opioid therapy (COT) for pain are referred, whether because of poor outcomes or aberrant behavior, the patients are often overtly opioid dependent, have other complex psychiatric issues, or are at high risk for opioid misuse if not frank dependence. In this context, it is reasonable to expect more methadone to be pre-

scribed in order to achieve adequate pain management.

In our current political climate coupled with professional ignorance about the disease of opioid dependence, it is understandable that access to adequate pain management care is woefully limited, particularly for opioid-dependent patients. In the case of our patient, one cannot help but wonder if her DIP was induced by stressors including the tapering of her methadone. Nonetheless, I maintain that an increase in the patient's dose of methadone was well indicated, if for no other reason than improved pain management.

It is a grievous situation when colleagues will no longer give or accept sound medical opinions about patient care out of fear of legal concerns or being considered a "problem" prescriber. This is not to blame anyone, especially colleagues or government. Fear and ignorance are not a good mix in any context, and are particularly problematic in medical care. I hope this case shines some light on the subject.

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