CASE REPORT

Use of implantable buprenorphine beyond FDA limit: A case report

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Campbell MC. Use of implantable buprenorphine beyond FDA limit: A case report. Addict Clin Res 2018;2(2):32-3.

Buprenorphine is used to treat opioid use disorders. Compliance can often be a clinical challenge. There are many patient factors involved in making oral buprenorphine a successful treatment. Implantable buprenorphine improves the chances of compliance and successful treatment. Currently, the FDA only approves implantable buprenorphine for one year of use. Presented is a case of implantable buprenorphine beyond the FDA limit.

Key Words: *Buprenorphine; Implant; Opioid*

INTRODUCTION

Buprenorphine implants received Food and Drug Administration (FDA) approval in May of 2016 (1). The implant consists of a set of four, 26 mm implantable rods, which are sub-dermally placed in the bicipital grove. The implants produce the plasma level equivalent of up to 8 mg of daily oral buprenorphine for up to six months (2). The implants are designed to be removed and either replaced or switched to another form of buprenorphine after six months. The FDA has approved buprenorphine implants for only one year of total use. The ability to prescribe, insert and remove buprenorphine implants is under the guidance of a FDA Risk Evaluation and Mitigation Strategies (REMS) program. Prescribing buprenorphine implants entail passing a written test, while insertion and removal involve passing a clinical practicum after a daylong training session. The buprenorphine implants impart significant advantages in compliance, reliable plasma levels of buprenorphine and low risk of diversion due to surgical placement (3). Despite these advantages, buprenorphine implants still carry a risk of addiction as an opioid. Diversion of oral buprenorphine has become a growing problem given the medicine community's attempt to decrease prescription opioids and the consequent boon of illicitly obtained opioids (4). Opioid use disorder patients often use illicit buprenorphine as a substitute for preferred opioids, to bridge between preferred substances, or to self-taper (5). Reliable forms of buprenorphine treatment are needed for successful treatment of opioid use disorders. Buprenorphine implants offer a long-term buprenorphine option with the potential for use beyond the one-year FDA approval period.

CASE REPORT

Patient G first sought care in August of 2012, for a variety of circumstances. He had recently lost both of his parents and was involved in a serious car accident. His primary symptoms of PTSD included significant anxiety, flashbacks and nightmares involving the accident and subsequent driving. He was treated with a combination of paroxetine and clonazepam. His extreme inability to ride comfortably in a motor vehicle precluded him from driving and he rarely drove himself in his ten-minute commute to work. The patient also carried a history of alcohol use disorder that was in long-term remission and maintained with Alcoholic Anonymous meetings. The patient's PTSD symptoms improved over the course of two years with medication management and concurrent cognitive behavioral therapy. The patient did report opioid usage for chronic pain symptoms but reported no symptoms of an opioid use disorder. Eventually, his follow-up lapsed, and he was not seen again until 2016.

When GH returned to the clinic in January of 2016, he again was under a great deal of duress but with different circumstances. At this point, he had several domestic disputes with his wife and son. The latter mostly had to do with his son's own struggle with opioids. The former seemed more likely due to relational difficulties that were heavily impacted by his own opioid use, which was strictly in medication form. Due to this domestic dispute, the patient was ultimately facing legal charges and possible jail time. He was inducted on 8mg of buprenorphine/naloxone at his request to aid in discontinuing his opioid medications in March of 2016.

Following his incarceration, the patient returned to clinic in July of 2016 for continued buprenorphine/naloxone treatment as well as concurrent group and individual alcohol and drug counseling. The patient had significant internal and external motivation to stay opioid free, as he wanted to mend his marriage and avoid further jail time via parole. The patient did very well on 8 mg of buprenorphine.

In the beginning of 2016, the option of buprenorphine implants was discussed with the patient. These discussions continued through the release of probuphine and subsequent REMS training courses. After his incarceration, G even spoke directly to Braeburn Pharmaceutical representatives to assuage his fears of this new buprenorphine modality. Even after the patient decided to try the buprenorphine implants, there was a considerable delay due to insurance confusion/coverage. Finally, in October of 2016, G became the clinic's first patient to receive buprenorphine implants for maintenance buprenorphine. He did require an extra 2mg of buprenorphine/naloxone film to maintain adequate control of cravings. He has given consecutive negative urine samples since starting the buprenorphine implants and otherwise leads a productive life with his wife. He is now off parole.

DISCUSSION

In September of 2018, G received his fifth set of buprenorphine implants. This would be the first documented case of a patient successfully maintained on buprenorphine implants over the FDA approved one year of usage. There were no complications either anatomically or pharmacologically from placement of buprenorphine implants in previously used sites. There were no difficulties with successive implant usage. It should be noted that previous long-term implantation has been documented at seven years, thus speaking to the safety of polyvinyl alcohol (PVA), which comprises the implant (6). Additionally, repeated use of similar technology in birth control implants has seen no adverse repercussions for use of similar sites anatomically (7).

CONCLUSION

The FDA approval of repeated applications of buprenorphine implants would seem self-evident given the need for more reliable forms or buprenorphine than once a day self-dosing. The technology and methods used for buprenorphine implants have been utilized for longer time between implants and overall longer time for usage in implantable birth control. The lack of FDA approval for buprenorphine implants past one-year stands as stumbling block for health insurance coverage. Given that the opioid crisis continues, all tools for treatment need easy availability and coverage.

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Received: October 30, 2018, Accepted: November 13, 2018, Published: November 17, 2018

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