MCSTAP Learning Case: Prescribing Vivitrol for a Pregnant Woman

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Brief Description of Clinical Case

The patient is a 28-year-old female with a history of severe opioid use disorder, currently in recovery for one year. She initially used naltrexone (Vivitrol) in early recovery; however, she has not been on any medications for several months. She attends 12-step meetings regularly. The patient recently became pregnant and is currently in her first trimester. She endorses a return of cravings for heroin and is fearful of relapse.

The patient reports that she has tried both Suboxone and methadone in the past; however, she did not find them helpful in maintaining recovery and reports that she misused both medications. She reports she has only had success with Vivitrol.

The patient is now requesting an urgent appointment for a Vivitrol shot. The PCP has experience in treating patients with opioid use disorder however is uneasy about administering Vivitrol to a pregnant female. He requests a consultation regarding the safety and appropriateness of administering Vivitrol to pregnant women.

Medications

Vivitrol 380mg injection

Caller Question

Is it safe and appropriate to administer Vivitrol to a patient who is currently pregnant in her first trimester?

Treatment Plan

We agreed that the best course of action was to administer the Vivitrol shot if appropriate (if no opioid use in prior 10 days) and to refer the patient to an obstetrician with experience in treating women with opioid use disorder, specifically with naltrexone/Vivitrol.

1. Continue to engage with the patient and provide support during this high-risk period.
2. Refer the patient to an OB who is experienced at treating patients with a history of opioid use disorder.
3. If the patient is requesting injection with Vivitrol, the risks of administering the medication and preventing relapse likely outweigh risks of withholding medication. The patient should be counseled on the risks of treatment with naltrexone and provide her consent for treatment.

Learning points

1. Naltrexone in pregnancy is classified as a Category C drug, which means animal reproduction studies have shown an adverse effect on the fetus, and there are no adequate and well-controlled studies in humans, but potential benefits may warrant the use of the drug in pregnant women despite potential risks.

2. Clinical practice guidelines recommend that if a patient being treated for naltrexone becomes pregnant and the risk for relapse is high, naltrexone should be continued after the patient is informed of the potential risks of continuing treatment and consent for ongoing treatment is obtained. If the patient subsequently relapses, consideration should be given to treatment with methadone or buprenorphine.[2]
3. A recent pilot study at Boston Medical Center compared six women taking naltrexone and 13 women taking buprenorphine. Results showed that no infants in the naltrexone group had Neonatal Abstinence Syndrome (NAS) compared with 92 percent in the buprenorphine group ($P<0.001$). Forty-six percent of the buprenorphine-exposed infants were treated for NAS versus 0 percent of the naltrexone-exposed infants ($P<0.001$). Naltrexone-exposed neonates had a shorter length of stay, mean 3.2 days versus 10.9 days ($P=0.008$).[3]
4. There are ongoing trials being conducted at Boston Medical Center and Massachusetts General Hospital.
5. A retrospective cohort study published in Australia in 2017 showed the use of implantable naltrexone in pregnancy was not associated with higher negative birth outcomes compared with methadone- and buprenorphine-exposed neonates. Also significant was that naltrexone- and buprenorphine-exposed neonates were not associated with the high rates of neonatal mortality and congenital anomalies seen in methadone-exposed neonates. Limitations are that this was not a controlled study.[1]

1. Kelly E, Hulse G. A Retrospective Cohort Study of Birth Outcomes in Neonates Exposed to Naltrexone in Utero: A Comparison with Methadone-, Buprenorphine- and Non-opioid-Exposed Neonates. Drugs 2017 Jul;77(11):1211-1219
2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction involving Opioid Use. J Addict Med. 2015;9(5):358-167.
3. Wachman EM et al. Naltrexone Treatment for Pregnant Women with Opioid Use Disorder Compared with Matched Buprenorphine Control Subjects. Clinical Therapeutics. 2019;41(9):1681-1689.