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Rapid Initiation of Extended Release Buprenorphine in Patients using Fentanyl and Fentanyl Analogs

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Introduction
During the 12 months ending October 2020, highly potent synthetic opioids, including fentanyl and fentanyl analogs, accounted for 81% (53,792 of 66,047) of all opioid overdose deaths in the US[1]. This case series from open-label studies evaluated initiating extended release buprenorphine (BUP-XR) following a single dose of 4 mg transmucosal buprenorphine (BUP-TM) in the challenging set of fentanyl-positive (FEN+) subjects[2] with opioid use disorder.
Methods
Eligible subjects abstained from opioids for at least 6h. Urine drug screens (UDS) and clinical opiate withdrawal scale (COWS) data were collected. When the COWS score was ≥8, 4 mg BUP-TM was administered. If the subject did not exhibit symptoms of hypersensitivity, precipitated withdrawal, or sedation after 1h, 300 mg of BUP-XR was injected and clinical assessments were completed in the clinic (48h) and as an outpatient (28d). Subjects could elect to receive 5 additional injections of BUP-XR and be followed for 24w.
Results
Twenty subjects were FEN+ by UDS but only 5 self-reported use of fentanyl. All 20 FEN+ subjects received BUP-TM, 18 received BUP-XR injection, 14 elected to receive the second injection and 11 subjects received all 6 injections. After BUP-XR injection, COWS scores decreased from a pre-BUP-XR mean±SD baseline of 13.7±3.1 (moderate withdrawal) to 7.8±4.2 (mild withdrawal) at 6h and to 4.6±3.5 (no active withdrawal) at 24h. Based upon adjudication committee assessment, 2 subjects experienced precipitated withdrawal during initiation, but still completed all 6 injections. After 24w, 9 of 10 retained subjects were negative for opioids by UDS. Fourteen subjects experienced adverse events, mostly withdrawal symptoms within 48h of injection.
Conclusion
Rapid initiation of BUP-XR 300 mg following a single 4 mg dose of BUP-TM in FEN+ subjects was well-tolerated with 24w retention and abstinence rates comparable to subjects using a broad range of opioids.[3] (ClinicalTrials.gov Identifiers: NCT03993392 and NCT04060654)

Conflicts

John Mariani has been a consultant, advisory board member and speaker with Indivior

Robert Dobbins is employed by Indivior

Amy Heath is employed by Indivior

Frank Gray is employed by Indivior

Howard Hassman declares no conflict of interest

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