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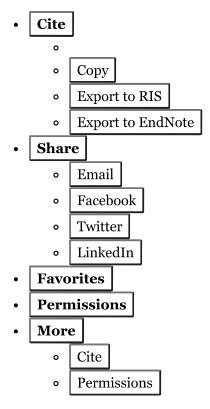
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Predictors of serious adverse drug events from opioids

Results from the Food and Drug Administration Adverse Events Reporting System

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Abstract

Background:

Opioids pose significant increased risk for serious adverse drug events (ADEs).

Purpose:

The purpose was to identify significant predictors and their associated magnitude of risk for serious life-threatening opioid ADEs.

Methods:

A post hoc design was used to examine predictors of opioid analgesics ADEs with Food and Drug Administration Adverse Events Reporting System (FAERS) data. The sample consisted of all eligible cases from the second quarter of the 2019 FAERS where an opioid analgesic was identified as the primary suspect for an ADE. Logistic regression was used to predict serious life-threatening ADEs. Final predictors included age, gender, misuse/substance use disorder, number of concurrent opioids; use of benzodiazepines, other sedatives, and antidepressants; and use of morphine, fentanyl, and oxycodone.

Results:

Life-threatening ADEs, excluding suicide and suicide attempts, comprised 19.9% of the cases. Protective factors that reduced risk included female gender, use of antidepressants, and use of morphine. Harmful factors that increased risk of a serious ADE included misuse/substance use disorder, use of benzodiazepines, and use of other sedatives. Persons taking an opioid with both a benzodiazepine and another sedative increased risk of a serious ADE by 18.78 times.

Implications for practice:

Results provide risk data helpful to share with people who use prescribed opioids for self-management of pain. Combination of opioids and clinically indicated antidepressants that do not both promote serotonin uptake inhibition may reduce risk for serious opioid ADEs. Practitioners should continue to avoid prescribing benzodiazepines and other sedatives when opioids are used.

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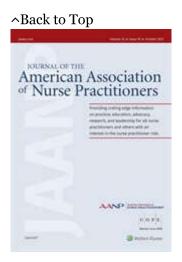
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