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Risk of hyponatremia after tramadol/acetaminophen single-pill combination therapy: A real-world study based on the OMOP-CDM database

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Objectives: Tramadol has been reported to cause hyponatremia but the evidence is conflicting. The risk of hyponatremia resulting from combination oral tramadol/acetaminophen (TA) therapy is thus unknown. This study examined whether, compared to acetaminophen (AA), TA use is associated with an increased risk of hyponatremia.

Methods: Hospital data compatible with the Observational Medical Outcomes Partnership – Common Data Model (OMOP-CDM; version 5.3) for 30,999 patients taking TA or AA from 2011 through 2020 were analyzed. New-onset hyponatremia was defined as a serum sodium level < 135 mEq/L within 10 days after drug initiation. The incidence rate ratio was calculated based on crude and 1:1 propensity-score-matched models. Subgroup analyses compared patients taking TA-extended release (TA-ER) and TA-immediate release (TA-IR) formulations.

Results: Among the 30,999 patients, 12,122 (39.1%) were aged > 65 years and 16,654 (53.7%) were male. Hyponatremia within 10 days developed in 1,613 (8.4%) of the 19,149 patients in the TA group; the incidence rate was higher than in the AA group (4.2%; 493 out of 11,850 cases). In the propensity-score-matched model, the incidence rate of hyponatremia in the TA group was 6.8 per 1,000 person-days (PD), which was 1.57-fold (1.31, 1.89) higher than that in the AA group (4.3 per 1,000 PD). In both the crude and propensity-score-matched models, the incidence rate of hyponatremia was significantly higher in the TA-ER than TA-IR sub-group.

Conclusions: In this real-world study, the risk of hyponatremia was higher in the TA than AA group, and in the TA-ER than TA-IR sub-group.