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Short-term risk of falls among initiators of controlled-release tapentadol versus oxycodone

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Is the presenter an HDR student? Yes.

Has this research been submitted or presented elsewhere? If so where and when? This work has been published as a preprint (<https://doi.org/10.64898/2026.01.14.26344133>). It has also been submitted to PLOS Medicine and is currently under peer-review.

Abstract

Background and Aims: Opioids are associated with increased risks of falls immediately following initiation. Clinical trials suggest sustained-release (SR) tapentadol has fewer adverse nervous system effects vs controlled-release (CR) oxycodone, but real-world safety is still unclear. We therefore compared risks of falls at 7, 14, and 28 days following initiation of tapentadol (SR) versus oxycodone (CR) in real-world clinical practice.

Design and Methods: We conducted an active comparator, new user cohort study using routinely collected data on NSW residents (2014-2020) from the MedIntel data platform. We included adults initiating tapentadol (SR) or oxycodone (CR). Our outcome was a composite measure of fall-related emergency department presentations, hospitalisations, or deaths. We used propensity score matching to adjust for confounding and calculated relative risks (RR) and absolute risk differences (RD), and estimated the number of people that would need to be treated with oxycodone (CR) vs tapentadol (SR) for one additional fall to occur (NNTH). We conducted subgroup analyses among people aged ≥ 65 and ≥ 80 years and by recent opioid exposure.

Results: We identified 103,924 tapentadol and 419,732 oxycodone initiators (103,758 matched). 74% were aged between 45-84 years; slightly more than half were female. Within 28 days of initiation, 652 (0.6%) oxycodone and 457 (0.4%) tapentadol initiators experienced a fall. Across all time points, tapentadol was associated with lower risks of falls vs oxycodone (7 days: RR 0.57 [95% CI 0.48 to 0.69]; 14 days: 0.62 [0.54 to 0.71]; 28 days: 0.70 [0.62 to 0.79]). Absolute differences were small (approximately 1-2 fewer falls per 1,000 patients treated), corresponding to NNTH for one additional fall ranging from 739 to 529. These patterns persisted regardless of recent opioid exposure or age. The greatest absolute differences were among opioid-naïve people aged ≥ 80 years (6-10 fewer falls/1,000, corresponding to NNTH ranging from 173 to 97). Fall risks were attenuated among people aged ≥ 80 years with recent opioid exposure.

Conclusions: Tapentadol (SR) was associated with a lower risk of falls than oxycodone (CR) within 28 days of initiation, although absolute differences were small. This may be an important consideration for older patients where the consequences of falls are most severe.

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