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Abuse Liability of Tapentadol is Significantly Lower Than Other Schedule II Opioids

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Introduction

- Tapentadol is a Schedule II opioid with a combination of μ -opioid activity and norepinephrine reuptake inhibition that is used for the management of moderate to severe acute and chronic pain.
- To date, a pattern of relatively low, although not absent, abuse liability has been found.
- This study included intentional abuse exposures reported to poison centers and cases of diversion to assess the abuse liability of tapentadol.

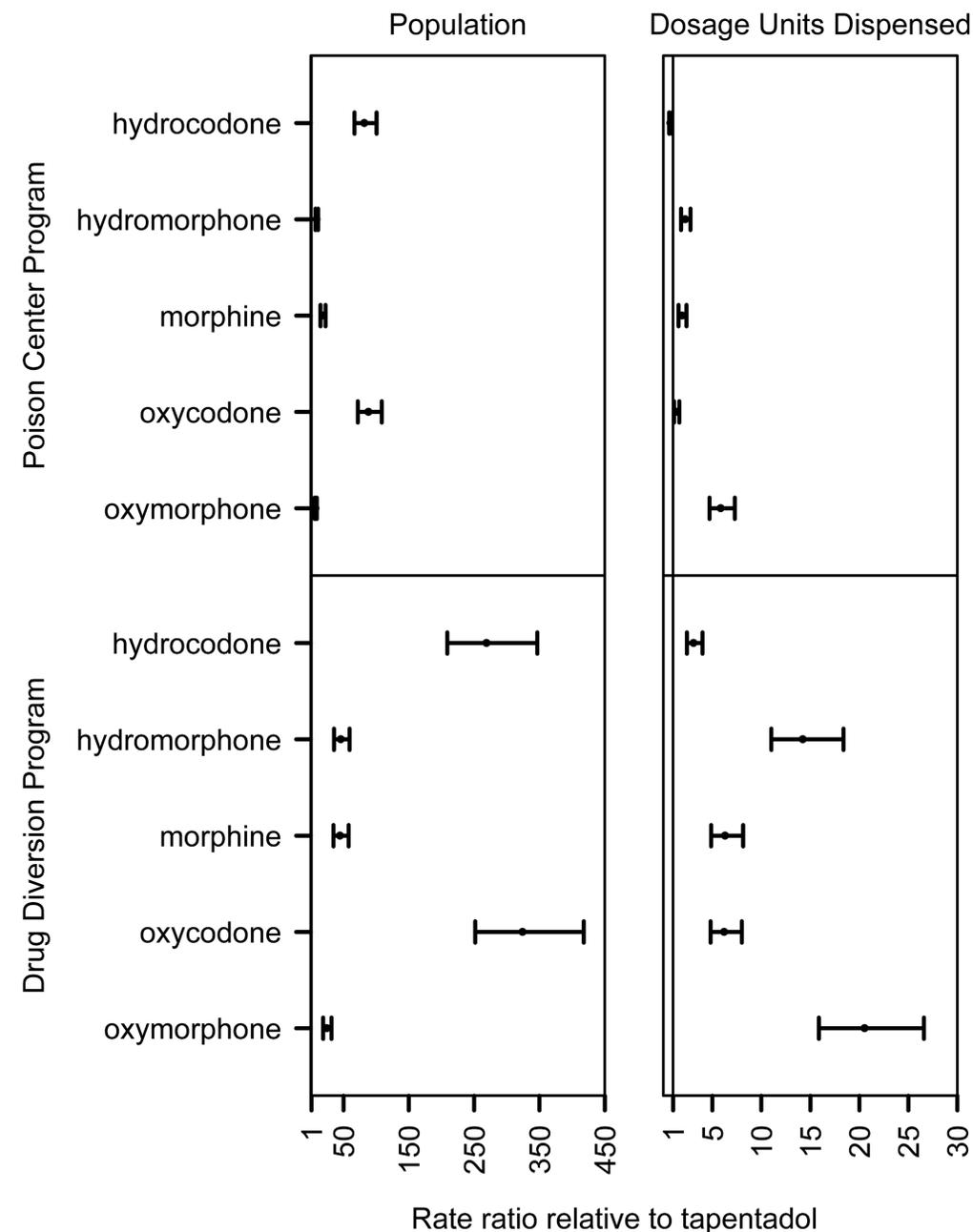
Methods

- The abuse and diversion rates for all formulations of tapentadol are compared to rates for other Schedule II opioids using data from the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System Poison Center and Drug Diversion Programs.
 - The RADARS System Poison Center Program obtains data from individuals within the general population and from healthcare providers who are seeking advice regarding potential toxic exposures, including exposures to prescription opioids and stimulants.
 - The RADARS System Drug Diversion Program conducts a quarterly survey of law enforcement investigators on the diversion of prescription opioid and stimulant products in their jurisdictions.
- Cumulative tapentadol rates per population and per dosage units dispensed are compared to those for hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone from October 2011 through December 2016 using Poisson regression.

Results

- The ratio of each comparator opioid rate relative to the tapentadol rate is presented in Figure 1.
- There were 92 intentional abuse exposure case reports (calls) involving tapentadol products during the study period. Per population, the rate of tapentadol intentional abuse was significantly lower than all comparator opioids ($p < 0.001$).
- The rate of tapentadol intentional abuse exposure case reports per dosage units dispensed was significantly lower than all comparator opioids ($p < 0.01$) except hydrocodone ($p = 0.002$).
- There were 60 cases of tapentadol diversion during the study period. Rates of tapentadol diversion per population and per dosage units dispensed were significantly lower than comparator opioids ($p < 0.001$).

Figure 1. Ratio of Comparator Opioids Rates to Tapentadol Rates with 95% Confidence Intervals



Note: Values greater than one indicate a rate higher relative to tapentadol. Confidence intervals that do not overlap 1 indicate that the tapentadol rate is significantly different than the comparator rate. Dosage units dispensed data are based on projections provided by QuintilesIMS[™] (Danbury, CT).

Conclusions

- Population rate findings suggest the overall public health burden of tapentadol abuse and diversion is low relative to other Schedule II opioids.
- Diversion of tapentadol is less frequent than other Schedule II opioid products when accounting for drug utilization (dosage units dispensed).
- Rates of tapentadol intentional abuse case reports per dosage units dispensed are lower than hydromorphone, morphine, oxycodone, and oxymorphone, but greater than hydrocodone.
- This analysis assesses abuse liability at the opioid molecule level. Given differences between the molecules, further research is needed to assess the impact of different formulations (e.g. immediate release versus extended release; single-entity or combination-products).

Limitations

- The Poison Center Program relies on spontaneous reports; therefore, the number of cases is underreported and drug identification may be inaccurate.
- Not all parts of the US have prescription drug diversion agencies, and thus data are subject to under-reporting and regional differences.

Disclosures

The RADARS System is supported by subscriptions from pharmaceutical manufacturers for surveillance, research and reporting services. RADARS System is the property of Denver Health and Hospital Authority, a political subdivision of the State of Colorado. Denver Health retains exclusive ownership of all data, databases and systems. Subscribers do not participate in data collection or analysis, nor do they have access to the raw data.

