RADARS® SYSTEM

Researched Abuse, Diversion and Addiction-Related Surveillance System

4th Quarter 2015 Technical Report

Number of Prescription Opioid Tablets/Capsules Ingested in Intentional Abuse Exposures Cases Reported to Poison Centers

Key Points:

1. The primary route of intentional abuse prescription opioid tablet/capsule mentions reported to the RADARS System Poison Center Program is ingestion.
2. The median (IQR) number of prescription opioid tablet/capsule ingested in intentional abuse exposures is 7 (3, 15) for Immediate-Release (IR) formulations and is 3 (2, 7) for Extended-Release (ER) formulations.
3. The percentage of IR tablet exposures involving more than 3 tablets/capsules (72.5%) is greater than the percentage of ER tablet exposures involving more than 3 tablets/capsules (47.7%).

Background

The primary reported route of intentional abuse of prescription opioid products is ingestion [1, 2]. While ingestion of intact prescription opioid products at or above the recommended doses does not provide a rapid onset of euphoria, ingestion produces euphoria with the least effort [2]. There are primarily two types of solid dosage forms of prescription opioids: Extended-Release (ER) and Immediate-Release (IR). ER drug product technology provides the ability to maintain therapeutic drug concentrations over a long period of time with less frequent dosing. There is typically more active drug in ER products compared to their IR counterparts. As of October 2015, the maximum ER oxycodone tablet strength sold in the US was 80 mg while the maximum IR oxycodone tablet strength was 30 mg [3]. For this reason, drug abusers may consume more IR tablets/capsules than ER tablets/capsules to achieve the desired euphoric effect. The purpose of this report is to highlight the prevalence of ingestion (swallowed whole) as a primary route of prescription opioid intentional abuse and compare the number of ER and IR tablets/capsules reported per case.

Methods

Data from the RADARS System Poison Center Program from January 1, 2013 to September 30, 2015 were used for these analyses. Intentional abuse exposures among individuals greater than 12 years old that involved tablet/capsule formulations of hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, tramadol, or tapentadol were included. Route, substance quantity, and quantity measurement were uniquely coded for each drug mentioned in a case. For the ER versus IR analysis, the inclusion criteria were mentions in which the only route mentioned was ingestion, the substance quantity was exact or estimated, and the quantity measurement was tablets/pills/capsules. The number of ER, IR, and not otherwise specified (NOS) tablets/capsules ingested for each case was calculated and Tukey boxplots were created to represent the distributions in each group. A Tukey box plots consist of solid lines for the 25^{th}, 50^{th} and 75^{th} percentiles and whiskers which are the nearest data points within the lower and upper bounds defined by 1.5 times the interquartile range. Points outside these lower and upper bounds are considered outliers, and were not shown in the plots due to extreme values.

The ER, IR, and NOS groups were then categorized as involving more than 3 tablets/capsules or 3 tablets/capsules or less. The percentage of cases involving more than 3 tablets/capsules in each group was determined and a Chi squared test was performed to compare proportions for the IR and ER groups. Sensitivity analyses were conducted by removing tramadol from the drug list and by limiting the data to cases in which the exact substance quantity was known.

Results

- Of the 9,751 intentional abuse prescription opioid tablet/capsule mentions for individuals greater than 12 years reported to RADARS System Poison Center Program from January 1, 2013 to September 30, 2015, 6,373 (65.4%) reported ingestion, 176 (1.8%) reported chewing first and then swallowing, 1,035 (10.6%) reported non-ingestion route (e.g. dermal, inhalation, injection, transmucosal, other), and 2,290 (23.5%) were unknown route.
- For the ER versus IR comparison, 3,349 (34.4%) met inclusion criteria.
- As shown in Figure 1, the median number of tablets/capsules ingested was greatest for the IR group and smallest for ER group.
- The interquartile range for the number of tablets/capsules ingested was largest for the IR group and smallest for the ER group.
- Figure 2 shows that the percentage of cases involving more than 3 tablets/capsules is largest for the IR group and smallest for the ER group.
- The difference in the percentage of cases involving more than 3 tablets/capsules between the IR and ER groups was statistically significant (p-value<0.001).
- Results were similar when tramadol was removed.
- Results were also similar when limited to cases in which the substance quantity was exact.

Figure 1: Boxplot for the Number of Tablets/Capsules Ingested for Intentional Abuse Exposures

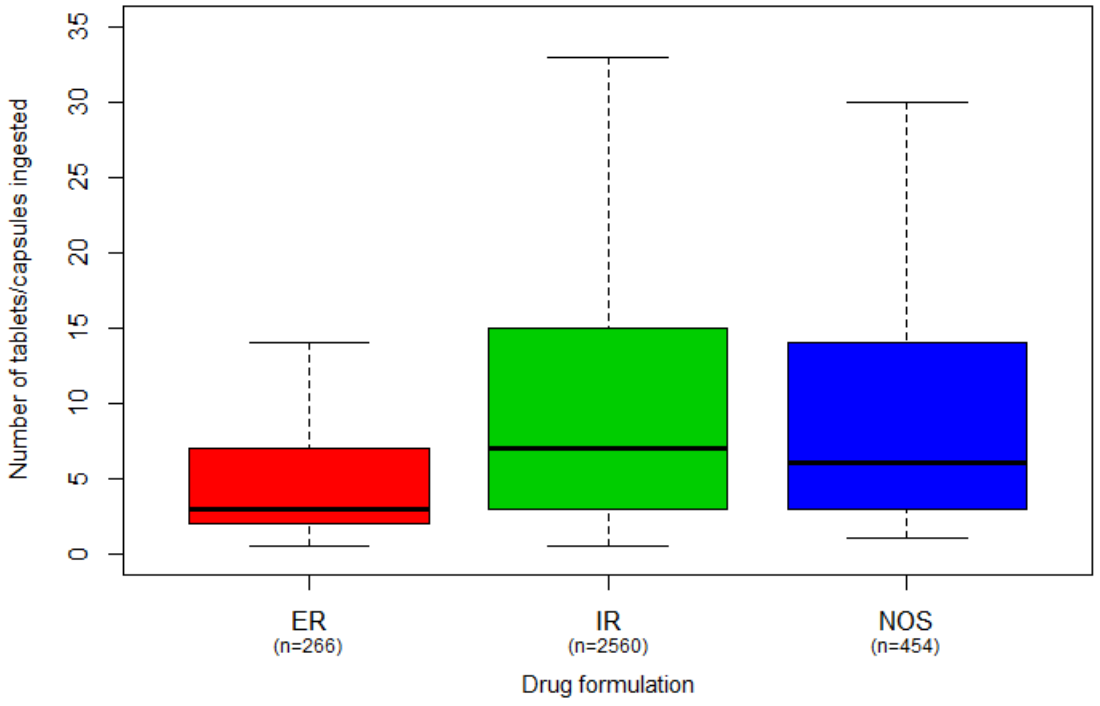
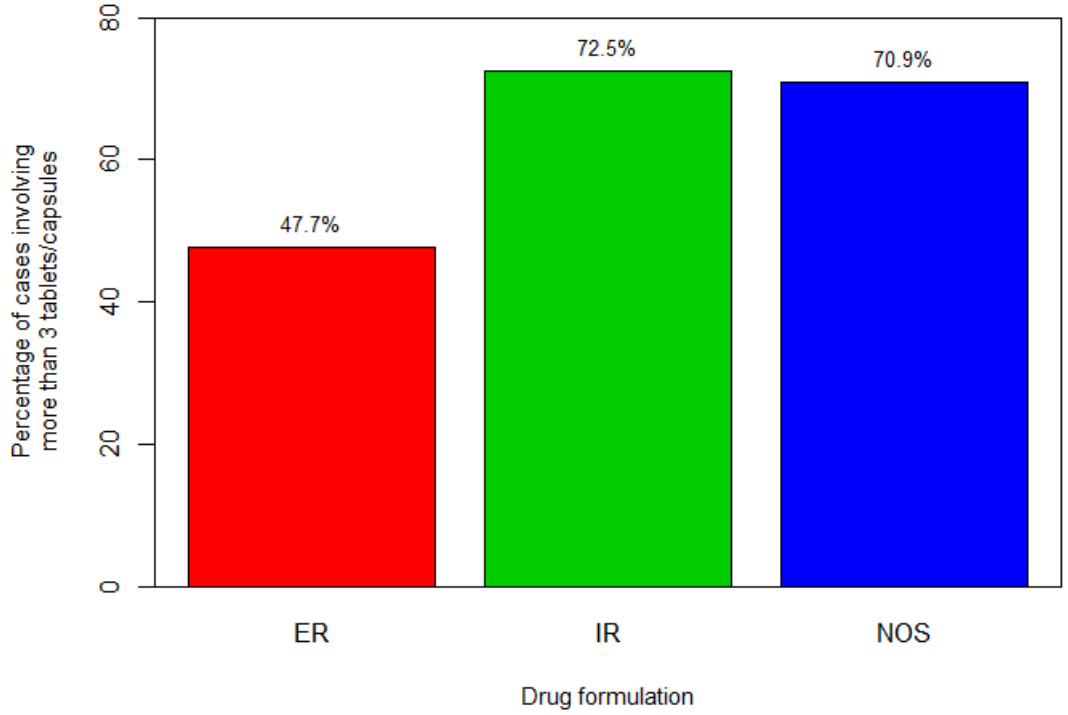


Figure 2: Percentage of Cases Involving More than 3 Tablets/Capsules for Intentional Abuse Exposures



Conclusions

The results suggest that abuse of IR tablets/capsules tended to involve the ingestion of more tablets than abuse of ER tablets/capsules. There is a large difference in the percentage of cases involving more than 3 tablets/capsules between ER and IR groups. A possible explanation for this discrepancy is that IR drugs typically have lower strengths compared to ER, thus individuals may not need to ingest as many ER tablets due to their high potency.

Limitations

Limitations exist in this study. The variables for the certainty, measurement unit, and quantity of pills ingested are not case reviewed. The quantity of pills ranged from 0.5 to 500. Classifying products as IR or ER can be a challenge as demonstrated by the number of not otherwise specified drugs (n=452), which exceeds the number of ER drugs (n=266). However the conclusions did not change with the removal of tramadol which accounted for 43% of the NOS category. It is likely that the results for NOS tablets/capsules are driven by IR tablets/capsules since these make up a large proportion of the market share [3].

Suggested Citation

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References

1. Food and Drug Administration, Center for Drug Evaluation and Research (CDER). (2015) *Abuse-Deterrent Opioids — Evaluation and Labeling: Guidance for Industry*. (Available from URL: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf)
2. Katz N, Dart RC, Bailey E, Trudeau J, Osgood E, Paillard F. Tampering with prescription opioids: nature and extent of the problem, health consequences, and solutions. *The American Journal of Drug and Alcohol Abuse.* 2011;37:205-217.
3. IMS Government Solutions, Inc., a subsidiary of IMS Health, Inc.