Tampering and Medical Outcomes in Poison Center Abuse and Misuse Nucynta® ER Exposures

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Introduction

- Nucynta® ER is an extended–release (ER) formulation of tapentadol, a Schedule II opioid analgesic used for the treatment of moderate to severe pain. Nucynta ER was released in the US in September 2011.
- Nucynta ER incorporates a crush-resistant technology intended to deter abuse via unintended routes of administration (e.g. inhalation, injection).
- The purpose of this analysis was to examine the risk of tampering and severe medical outcomes for abuse and misuse exposures involving Nucynta ER compared to exposures involving non-abuse deterrent (ADF) ER opioid tablets/capsules.

Methods

- Data from the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System Poison Center Program were used.
- Inclusion criteria:
  - Exposure occurred between July 2011 and March 2016
  - Exposure involved a singled substance of either Nucynta ER or a non-ADF ER opioid tablets/capsules (hydrocodone, hydromorphone, morphine, oxycodone, and oxymorphone excluding FDA approve ADF labled products: OxyContin®, EMBEDA®, Hysingla™ ER, Targiniq® ER, and Zohydro® ER)
  - Exposure reason was categorized as intentional abuse or intentional misuse
  - Medical outcome and route of administration were known
- Use via any route other than ingestion alone was categorized as tampering.
- The relative risk (RR) of tampering with Nucynta ER compared to non-ADF ER opioid tablets/capsules was calculated with the 95% confidence interval (CI).
- Fisher's exact test was used to examine the proportion of cases that resulted in a major medical outcome of death between the two groups.

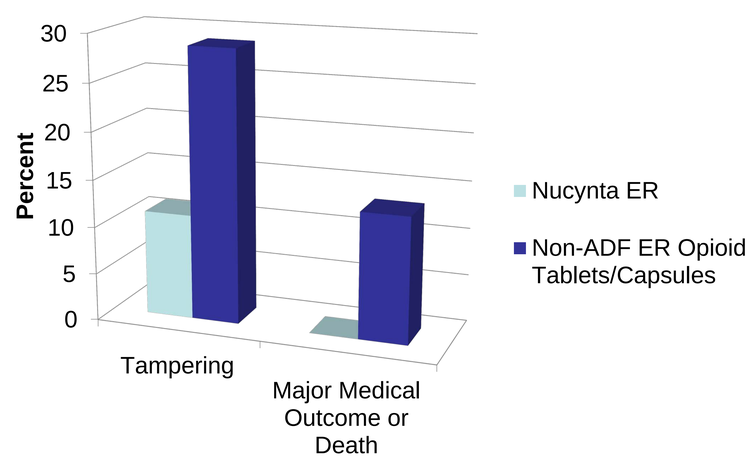
Table 1. Tampering among Nucynta ER and Non-ADF ER Opioid Tablet/Capsule Abuse and Misuse Cases

Drug	Tampering	No Tampering
Nucynta ER (n=36)	4 (11.1%)	32 (88.9%)
Non-ADF Opioid Tablets/Capsules (n=526)	151 (28.7%)	375 (71.3%)

Table 2. Major Medical Outcomes or Deaths among Nucynta ER and Non-ADF ER Opioid Tablet/Capsule Abuse and Misuse Cases

Drug	Major Medical Outcome or Death	No Major Medical Outcome or Death
Nucynta ER (n=36)	0 (0.0%)	36 (100.0%)
Non-ADF Opioid Tablets/Capsules (n=526)	70 (13.3%)	456 (86.7%)

Figure 1. Cases Involving Tampering or Resulting in Major Medical Outcomes or Deaths by Drug Group



The RADARS® System is part of Denver Health and Hospital Authority, a division of the state of Colorado. It is supported by subscriptions from pharmaceutical manufacturers.

Results

- There were 36 Nucynta ER cases and 526 non-ADF ER opioid tablet/capsule cases of included in the study.
- Of these, 4 (11.1%) Nucynta ER cases and 151 (28.7%) non-ADF ER opioid tablet/capsule cases of involved tampering.
- Non-ADF opioid tablet/capsule cases were 2.58 (95% CI: 1.02, 6.57) times more likely to involve tampering than Nucynta ER cases.
- There were no Nucynta ER cases and 70 (13.3%) non-ADF ER opioids tablet/capsule cases that resulted in a major medical outcome or death. This difference in proportions was statistically significant (p-value=0.019).

Conclusions

- These data show that Nucynta ER abuse and misuse cases are less likely to report tampering compared to non-ADF ER opioid tablet/capsule cases.
- There were no reports of a major medical outcome or death among abuse and misuse cases involving Nucynta ER.
- Prescription opioids with abuse deterrent properties can reduce abuse and misuse as well as severity of medical outcomes and should be considered one approach to addressing this significant public health issue.

Limitations

- Poison Center data are self-reported and may reflect a bias towards more severe medical outcomes.
- Poison Center data may underestimate the number of drug exposures in the population.
- The number of Nucynta ER cases was small, so statistical power is low.