Abuse and Misuse of XTAMPZA[®] ER Relative to Other Opioid Analgesics

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INTRODUCTION

•XTAMPZA[®] ER is an abuse deterrent ER oxycodone product that uses DETERx [®] technology designed to discourage manipulation

•The FDA has granted XTAMPZA ER abuse-deterrent labeling with respect to oral, nasal, and intravenous routes of administration

•This study compares rates of abuse and misuse of XTAMPZA ER to other opioid analgesics using two post-marketing surveillance data sources

METHODS

- Data from 2018 through 2020 from two Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System data sources:
- **Poison Center Program:** rates of intentional abuse/misuse/unknown exposures from 53 of 55 poison centers compared between drug groups using Poisson regression
- Treatment Center Programs Combined: respondents entering treatment for opioid use disorders (OUD) completed an anonymous survey in which they selected products used in the past month to get high. Odds of past month abuse endorsement were compared between drug groups using logistic regression
- Comparisons were adjusted for prescriptions dispensed or morphine equivalent grams dispensed information estimates obtained from the IQVIA® (Danbury, CT) US-Based Longitudinal Prescription Data
- XTAMPZA ER was compared to two groups: other abuse deterrent formulation (ADF) ER opioids and immediate-release (IR) oxycodone (Table 1)
- Multiple imputation was used to address unspecified/missing product information by active pharmaceutical ingredient
- Prevalence of unintended routes of administration (ROA) was assessed

DISCLOSURE

The RADARS[®] System is supported by subscriptions from pharmaceutical manufacturers, government and non-government agencies 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, nor do they have access to the raw data. This research was sponsored by Collegium Pharmaceutical. XTAMPZA[®] ER is a registered trademark of Collegium Pharmaceutical.

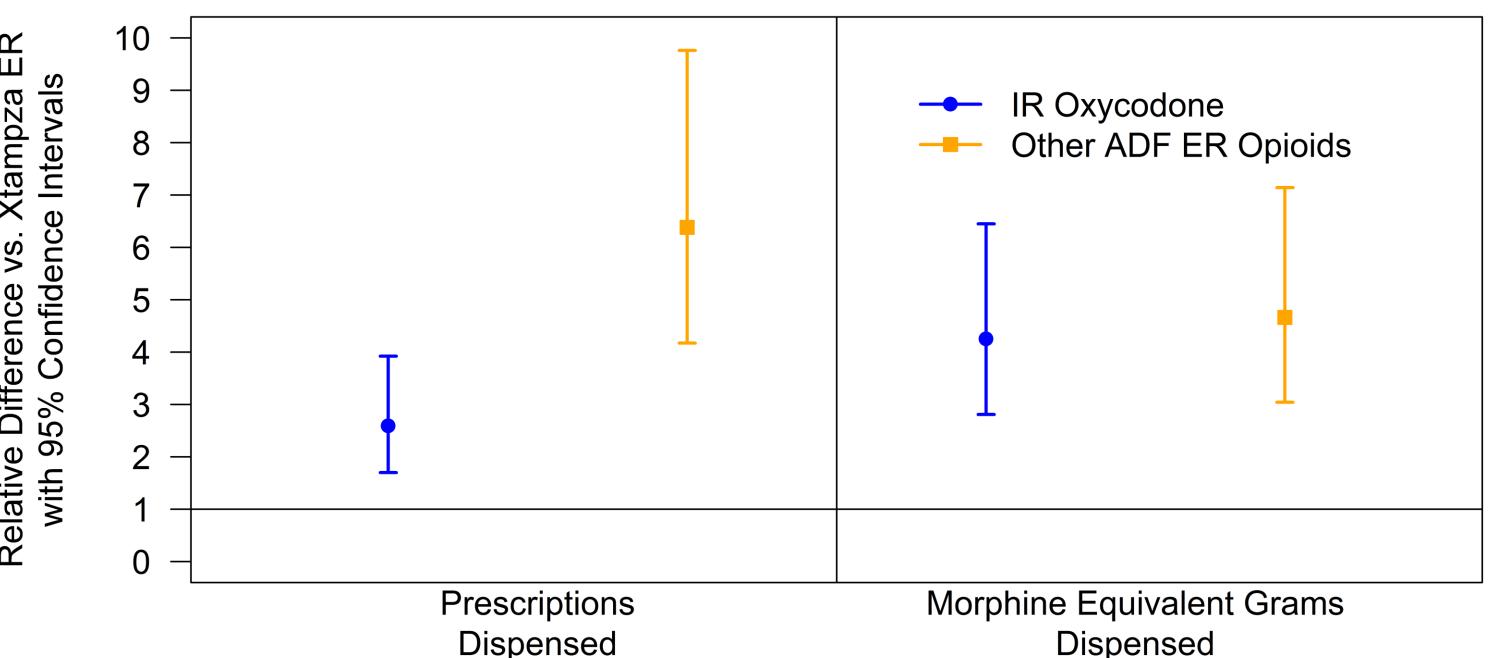
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RESULTS

Table 1. Prescriptions Dispensed by Drug Group, 2018-2020

Drug Group	Prescriptions Dispensed	Percentage within Drug Group
XTAMPZA [®] ER	1,266,095	100.0%
ADF ER Opioids	6,432,576	100.0%
ARYMO [®] ER	15,784	0.3%
EMBEDA®	256,241	9.8%
HYSINGLA [®] ER	489,934	7.6%
MORPHABOND [®] ER	93,170	1.5%
OXYCONTIN®	5,577,447	86.7%
IR Oxycodone	116,248,823	100.0%
Combination	68,423,877	58.9%
Single entity	47,824,946	41.1%

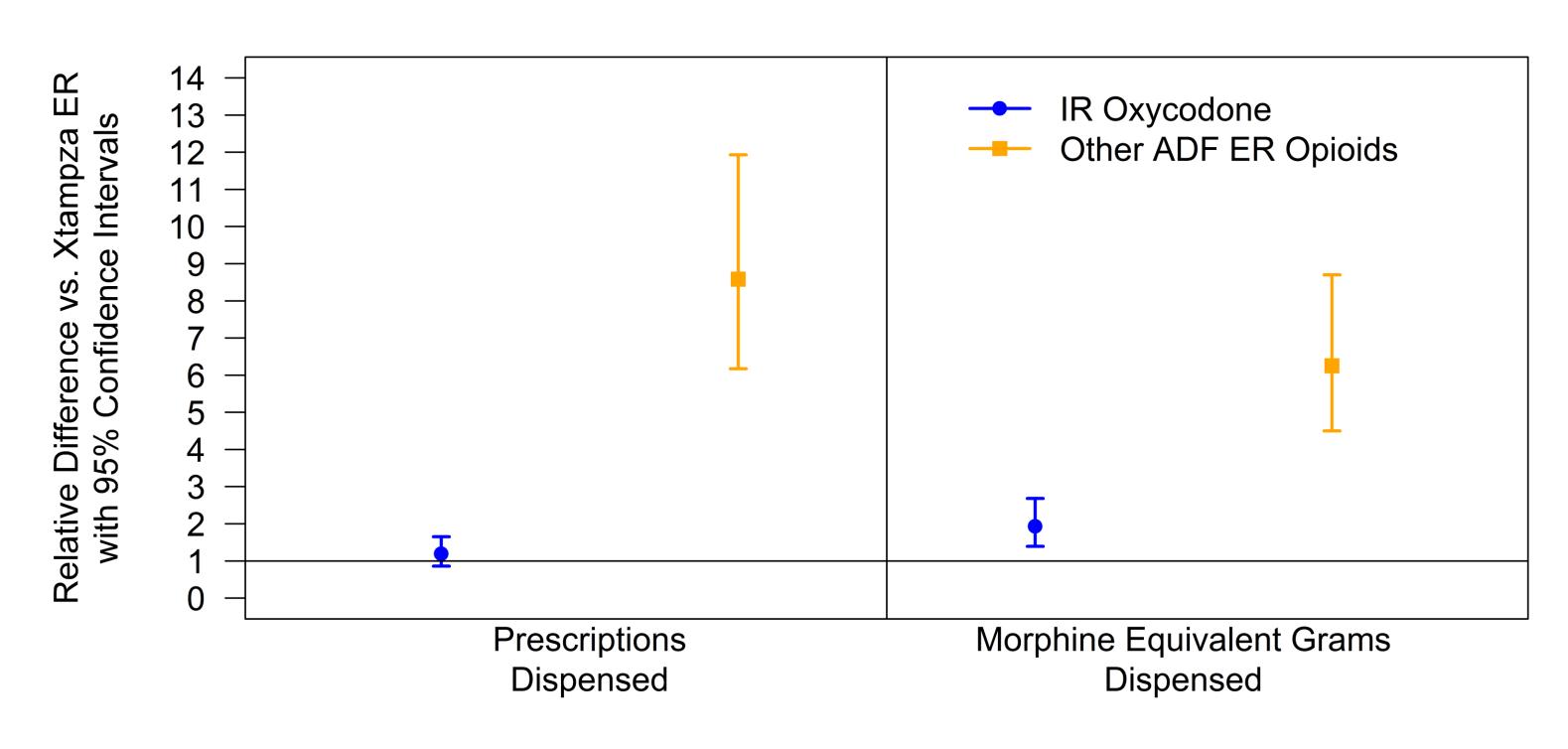
Figure 1: Ratio of Exposure Rates Relative to XTAMPZA ER by **Drug Group with 95% CI, RADARS[®] System Poison Center Program, 2018 – 2020**





Dispensed

Figure 2: Ratio of Odds of Abuse Relative to XTAMPZA ER by Drug Group with 95% CI, RADARS® System Treatment Center Programs Combined, 2018 – 2020



KEY RESULTS

- XTAMPZA ER (Figure 2)

CONCLUSION

comparators

LIMITATIONS

- data



•Comparator opioids were all statistically significantly greater than for XTAMPZA ER for both utilization measures (Figure 1)

•Except for IR oxycodone per prescription dispensed, utilization-adjusted odds of past month abuse were statistically greater for comparator drug groups than for

•No abuse/misuse XTAMPZA ER exposures involved unintended ROA. Prevalence of abuse by unintended ROA was lower for XTAMPZA ER than comparators among individuals with OUD

•Abuse and misuse exposures of XTAMPZA ER are infrequent relative to

 Abuse and misuse were self-reported in both programs and false positives may disproportionately inflate estimates of less frequent events

Results are based on three years and may change with additional years of