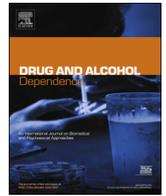




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Short communication

Incidence of future arrests in adults involved in the criminal justice system with opioid use disorder receiving extended release naltrexone compared to treatment as usual

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ABSTRACT

Background: Criminal justice involved (CJS) populations with opioid use disorder (OUD) have high rates of relapse, future arrests, and death upon release. While medication for OUD (MOUD) reduces opioid relapse, concerns regarding diversion and stigma limit treatment in CJS populations. Extended release naltrexone (XR-NTX), as an opioid antagonist, may be more acceptable to CJS administrators. However, the impact of XR-NTX on criminal recidivism remains unknown.

Methods: Arrest data from a published randomized trial comparing XR-NTX to treatment as usual (TAU) was captured by self-report and official state arrest records. Comparisons of future arrests, time to first arrest and total number of arrests were performed using chi square tests and multivariable generalized regression models. Secondary outcomes explored differences in arrests by type and severity of crime, use of opioid and other drugs, and study phase.

Results: Of 308 participants randomized, 300 had arrest data. The incidence of arrests did not differ between XR-NTX (47.6%) and TAU (42.5%) participants. (ChiSq $p = 0.37$). Additionally, there was no significant difference in time to first arrest (adjusted HR 1.35, CI 0.96–1.89) and number of arrests per participant (adjusted IR 1.33, CI 0.78–2.27). Controlling for gender, age, previous criminal activity, and use of non-opioid drugs, logistic regression demonstrated no significant difference in incidence of arrests between groups (adjusted OR 1.38, 95% CI 0.85–2.22).

Conclusions: We detected no significant difference in arrests between CJS participants with OUD randomized to XR-NTX or TAU. Despite its efficacy in reducing opioid use, XR-NTX alone may be insufficient to reduce criminal recidivism.

1. Introduction

Opioid use disorders (OUDs) are prevalent in the United States criminal justice system (CJS). Of individuals entering prison, 80% have a history of substance use, of which 20% suffer from OUDs. (Rich et al., 2005) Medication for OUD (MOUD), including methadone or

buprenorphine, reduces relapse, (Dolan et al., 2003; Gryczynski et al., 2012) improves outpatient treatment enrollment, (Hedrich et al., 2012; Magura et al., 2009; Schwartz et al., 2006) and may reduce future arrests, though the association with criminal recidivism remains uncertain (Bukten et al., 2012; Gordon et al., 2017a,b; Schwartz et al., 2009; Werb et al., 2008; Gordon et al., 2018). However, concerns

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regarding diversion, stigma, and a shortage of licensed providers limit MOUD in CJS populations (Belenko et al., 2013). With few treatment options, continued illicit opioid use (PEW Charitable Trusts, 2017) is associated with increased future arrests, re-incarceration, and death (Gordon et al., 2017a,b).

Extended release naltrexone (XR-NTX), formulated as a once monthly injection, has been shown to reduce opioid relapse in CJS populations (Comer et al., 2006; Krupitsky et al., 2011; Lee et al., 2016). As a non-scheduled opioid antagonist, XR-NTX is not burdened with the stigma, potential for abuse, or withdrawal after cessation of traditional MOUD, and is more acceptable to CJS administrators (Finigan et al., 2011). Yet the impact of XR-NTX on criminal recidivism is uncertain. Small trials have suggested naltrexone reduces parole violations (Coviello et al., 2010) and future arrests (Gordon et al., 2015). However, loss to follow-up, small sample sizes, and confounds by indication limit these results.

Our study examines the incidence of documented arrests of CJS participants previously randomized to XR-NTX compared to treatment as usual (TAU; Lee et al., 2016). We hypothesize participants randomized to XR-NTX will demonstrate fewer arrests.

2. Materials and methods

This secondary analysis examines previously collected data from a randomized trial evaluating XR-NTX in an adult CJS population with a history of OUD. Briefly, the original study was a five-site, open-label effectiveness trial, randomizing CJS adults with a history of OUD into a 24-week XR-NTX treatment or TAU protocol. The XR-NTX group received an initial injection of 380 mg depot naltrexone then subsequent injections every four weeks during the six-month treatment phase. The TAU protocol included referrals to OUD resources, including methadone and buprenorphine providers where available. Follow up visits with urine drug screening occurred every two weeks during the treatment phase and at weeks 27, 52, and 78 of follow-up. All patients received medical and opioid counseling at scheduled follow-up visits. (Lee et al., 2015).

2.1. Data sources

Participants completed demographic and background data, including self-reported criminal activity, prior to study enrollment. Hospitalizations for medical illness, detoxification, and psychiatric stabilization were collected at the start of the study and at four-week intervals until week 25, then at weeks 27, 52, and 78 of follow-up.

Two data forms were collected specific to arrests: the Crime and Legal Activities (CLA) survey and the Criminal Record Review (CRR) form. The CLA assessed self-reported arrests, incarcerations and convictions, at four-week intervals until week 25, and then weeks 27, 52, and 78 of follow up. The CRR form collected arrest data obtained from local and/or state authorities at the end of the study, including arrest date, type, crime, and disposition during the study period.

2.2. Data management

Records from each data source were used to create a combined data set. CRR data were used as the primary source for determining arrest outcomes. To capture missed arrests in other jurisdictions, the CLA self-reports were cross-referenced with CRR arrest records to maximize participant arrest information. If no CRR records were found for an individual but they had self-reported arrests, the participant's outcomes reflected their self-reported arrest activity. Additionally, if an individual had one or more arrest records, as well as self-reported arrests, the self-reported arrest information was added to the participant's arrest record.

Authors W.S. and P.F. independently coded all arrests in accordance with National Incident Based Reporting System (NIBRS) guidelines

(Federal Bureau of Investigation, 2012). The NIBRS is used by law enforcement to report data to government agencies, and defines crimes against persons, property, or society. Crimes against persons include homicide, kidnapping, and assault. Crimes against property include burglary, fraud, and theft. Crimes against society include drug offenses, parole violations, and prostitution. No disagreements in coding occurred.

The CLA survey was incomplete for 11 participants (7 in TAU group and 4 in XR-NTX group) and CRR reports were not available for 10 participants (2 in TAU group, 8 in XR-NTX group). Overall agreement between the CLA and CRR report was moderate with a kappa coefficient of 0.47 (95% CI 0.36–0.57). For the final dataset, the CLA contributed 27 arrests to CRR data (TAU: 3 assaults, 2 drug offenses, 1 larceny, 1 disorderly conduct, 1 trespass, 7 other offenses, 12 parole violations, XR-NTX: 1 drug offense, 1 larceny, 1 trespass, 1 other offense, 4 parole violations).

2.3. Outcomes

The primary outcome was the incidence of reported arrests during the study period among participants randomized to XR-NTX compared to TAU. In addition to arrest incidence, the total number of arrests and the time to first arrest were evaluated.

Secondary outcomes included comparisons of arrests stratified by study phase (treatment and follow-up), use of opioid and non-opioid drugs, and NIBRS crime category (person, property, society).

2.4. Analysis

Non-weighted kappa statistics compared reported arrests in the CRR report and the CLA survey data. Generalized linear models evaluated arrest differences between groups, adjusted for overdispersion and zero-inflation when appropriate. Participant factors, including participant age, gender, arrest severity, and positive test for non-opioid drug during study were included as covariates in adjusted models. Days at risk, defined as days not in a controlled environment (medical or psychiatric hospitalization or incarceration), was incorporated into regression analysis. Data were analyzed using SAS v.9.4 statistical software package.

Given concerns of confounding by indication due to patient self-selection, we deferred hypothesis testing evaluating treatment adherence, relapse, and other MAT use. Instead, results are presented using descriptive statistics.

3. Results

3.1. Baseline

Prior to randomization, pre-study arrests were similar between groups, including crimes against persons (XR-NTX 44% vs TAU 42%), against property (XR-NTX 35% vs TAU 34%), against society (XR-NTX 19% vs TAU 22%), and drug offenses (XR-NTX 84% vs TAU 85%). Thirty participants self-reported buprenorphine or methadone use during the study period (TAU 24 (15%), XR-NTX 6 (4%)). The majority of participants, (83%) self-reported buprenorphine or methadone use after a documented study relapse. Data regarding adherence and total duration of buprenorphine or methadone therapy were not collected.

3.2. Primary outcome

Of the 308 participants originally randomized, 300 had arrest data available during the study. The most frequent recorded arrests included drug offenses (XR-NTX N = 33, 21.6%, TAU N = 29, 18.7%), parole violations (XR-NTX N = 23, 15%, TAU N = 30, 19.4%), and larceny (XR-NTX N = 25, 16.3%, TAU N = 24, 15.5%) (Table 1).

The incidence of arrests did not differ between XR-NTX (47.6%) and

Table 1

Number of study participants arrested for each type of crime (at least once), categorized by group (NTX vs TAU). There were no arrests for: Arson, Embezzlement, Gambling, Homicide, Kidnapping, Vehicle Theft, Pornography, Sex Crimes.

Crime ¹	NTX (N = 153)	TAU (N = 155)
Drug offense	33 (21.6%)	29 (18.7%)
Parole violation	23 (15.0%)	30 (19.4%)
Larceny	25 (16.3%)	24 (15.5%)
Other offense ²	20 (13.1%)	22 (14.2%)
Assault	15 (9.8%)	8 (5.2%)
Trespass	7 (4.6%)	6 (3.9%)
Stolen property	5 (3.3%)	4 (2.6%)
Weapons violation	5 (3.3%)	1 (0.7%)
Vandalism	4 (2.6%)	1 (0.7%)
Burglary	3 (2.0%)	3 (1.9%)
Disorderly conduct	2 (1.3%)	2 (1.3%)
DUI	2 (1.3%)	2 (1.3%)
Robbery	2 (1.3%)	2 (1.3%)
Fraud	2 (1.3%)	1 (0.7%)

¹ Participant could have been arrested for more than one crime.

² Other offenses include: reckless endangerment, possession of instrument of crime, public urination, conspiracy, fugitive from justice, obstruction of gov't administration, resisting arrest, unauthorized sale of mass transit services, unknown offense.

TAU (42.5%) participants. (ChiSq $p = 0.37$) Controlling for gender, age, previous criminal activity, arrest severity, and use of non-opioid illicit drugs, multivariable logistic regression demonstrated no significant difference in incidence of arrests between XR-NTX and TAU groups (adjusted OR 1.38, 95% CI 0.85–2.22).

Number of arrests per participant was not significantly different between XR-NTX and TAU groups (adjusted IR 1.33, CI 0.78–2.27). A total of 87 participants had one arrest (XR-NTX 43, TAU 44), 30 had 2 arrests (XR-NTX 16, TAU 14), 10 had 3 arrests (XR-NTX 6, TAU 4), and 8 had 4 or more arrests (XR-NTX 5, TAU 3). Additionally, time to first arrest was not significantly different between groups (adjusted HR 1.35, CI 0.96–1.89). XR-NTX participants had a mean time to first arrest of 206 days (SD 144.2) whereas TAU participants had a mean time to first arrest of 253 days (SD 154.5).

3.3. Secondary outcomes

Category of crime did not differ between groups (OR 1.26 for crime against person compared to society, 95% CI 0.67–2.35, OR = 0.96 for crime against property compared to society, 95% CI 0.5–1.84). The incidence of first arrest during the 24-week study period and 54-week follow up did not differ between groups (XR-NTX 52.5% first arrest during study compared to TAU 40% first arrest during study, ChiSq

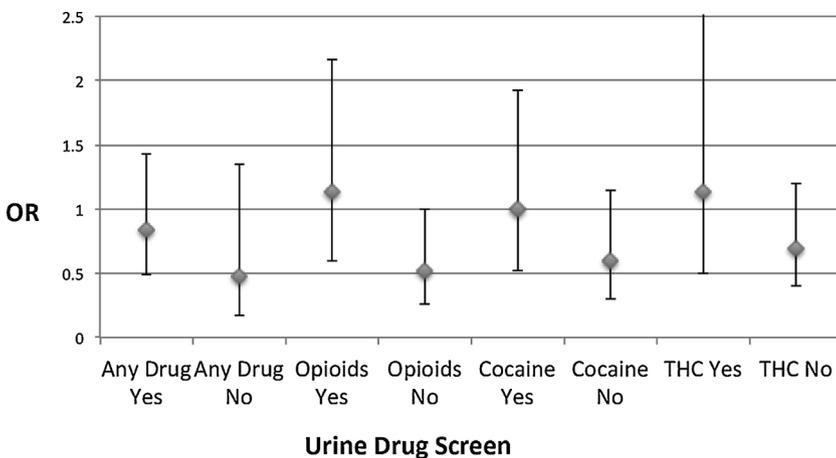


Fig. 1. Odds of Arrest: XR-NTX versus TAU by Urine Drug Screen.

Note: Odds of arrest (with 95%CI) of participants randomized to XR-NTX compared to TAU, stratified by drug use as determined by positive urine drug screen or self-report (any drug, opioids, cocaine, THC (Tetrahydrocannabinol)). No significant differences in odds of arrest occurred among XR-NTX participants compared to TAU. OR greater than 1 indicate participants were more likely to be arrested in the XR-NTX group.

$p = 0.20$). Odds of arrest were not significantly different in XR-NTX and TAU participants stratified by opioid and non-opioid drug use (Fig. 1). Finally, participant age, gender, and severity of criminal arrest prior to randomization was not associated with differences in arrests.

3.4. Treatment adherence, relapse and arrests

Of the 152 participants who did not relapse during the study, 56 attended all visits and 15 (27%) were arrested. In comparison, 96 missed one or more visits, of which 47 (49%) were arrested. In the 148 patients with a positive opioid screen, 73 (49%) were arrested. For those 73 participants who relapsed (positive opioid screen) and were arrested, 64 (88%) had a recorded relapse prior to their documented arrest.

4. Discussion

Observational and community-based research has demonstrated lower arrest rates in participants who engage and are retained in MOUD treatment programs (Gossop et al., 2000, 2005; Rothbard et al., 1999; van der Zanden et al., 2007; Lamey et al., 2012; Bukten et al., 2012). However, our study found that randomization to XR-NTX for OUD did not significantly decrease the incidence, total number, or time to first arrest in a CJS population. Though our results initially appear contrary to established literature, our findings are consistent with previous randomized trials that have also failed to find a consistent decrease in criminal recidivism in MOUD participants (Gordon et al., 2018; Magura et al., 2009; Schwartz et al., 2012). A 2015 Cochrane review concluded, when compared to non-pharmacotherapy based treatment, randomization to MOUD was not independently associated with reduced criminal activity (Perry et al., 2015).

The discrepancy between observational community studies and randomized trials on criminal recidivism may be attributed to unmeasured confounding. A combination of factors, including personal traits, economic hardships, and societal stressors all influence the likelihood of opioid use, relapse, and criminal activity. Observational study participants, by self-selecting treatments, create unmatched groups that contribute a different mix of intrinsic and social factors to the study. The combination of a different case-mix receiving different treatments leads to the observed significant decrease in arrest rates (Kinlock et al., 2009). In contrast to self-selecting treatment, randomization controls for unmeasured confounding factors. Results, therefore, can be attributed to the study treatment, providing a less biased estimated association of MOUD on arrests among CJS participants with OUD.

Our treatment retention and relapse data suggest that intrinsic, unmeasured confounding might explain the reduction in criminal recidivism found in observational studies. In contrast to our primary

outcome, participants who completed all study sessions and avoided relapse appeared to have a lower proportion of arrest. Because participants were not randomized to relapse or treatment adherence, it appears likely that the differences in arrest rates were, in part, attributable to participants' unmeasured intrinsic factors, such as social supports, employment, and social affiliations. Because of the influence of unmeasured confounders, we did not include relapse and treatment adherence in formal hypothesis testing.

Rather than MOUD independently reducing future arrests, it is likely that the mix of certain intrinsic factors combined with MOUD may promote adherence, abstinence, and lower criminal recidivism. Future research should focus on identifying case mix factors that are associated with OUD treatment retention to help providers effectively match CJS populations with individualized treatment modalities to promote retention and decrease criminal recidivism (Røislien et al., 2014).

4.1. Limitations

Inaccurate reporting of arrests may have introduced bias. The CLA and CRR forms demonstrated only moderate agreement, with both surveys containing inconsistencies and missing data. The difficulty of obtaining consistent, reproducible data on arrests in our study highlights the larger problem of accurately estimating arrests and convictions in CJS populations with OUD. We attempted to minimize recall bias by supplementing law enforcement reports with self-reported survey data. However, as we are unable to verify the true number of arrests, our incidence rates should be approached as estimates.

Additionally, although our analysis is unique in that it utilizes data from a randomized trial of XR-NTX over five different sites, the absolute number of participants remains small, with an estimated 80% power to detect a 15% or greater difference in criminal activity. While our trial benefits from randomization to minimize confounding by indication, our study was not powered to detect small differences in arrest rates between groups.

Further, the TAU group received counseling and OUD resources, with some participants' self-reporting methadone or buprenorphine use. With frequent study visits, the TAU group may have had a more aggressive intervention than many CJS populations normally receive, thus contributing to our null findings. However, our study question addressed the influence of XR-NTX compared to a real-world community referral treatment group; caution should be used in overgeneralization of our results.

5. Conclusion

Consistent with prior randomized trials, we found no significant difference in future arrests between CJS participants with OUD randomized to XR-NTX. Despite its efficacy in reducing opioid use, XR-NTX alone may be insufficient to independently reduce criminal recidivism.

Contributors

William Soares was involved in study design, data analysis, coding and publication. Donna Wilson was involved in study design and data analysis as the lead statistician. Michael Gordon was involved in study design, data analysis and manuscript revision. Joshua Lee, Edward Nunes and Charles O'Brien were involved in study design, data collection and manuscript revision. Milvin Schroff served as a summer scholar student, involved in background, IRB application and coding of data. Peter Friedmann was involved in study design, data analysis and manuscript revision. All authors have read and approved the final manuscript.

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Conflicts of interest

There are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome. The original randomized trial for which the data set was established now two years ago did receive in-kind medication from Alkermes; however, there was no financial or in-kind support in the design and completion of the current study.

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