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Extended-Release Naltrexone Versus Buprenorphine-Naloxone to Treat Opioid Use Disorder among Black Adults

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Abstract

Few studies examine the effectiveness of treatments for opioid use disorder (OUD) among Black individuals despite recent evidence suggesting opioid overdose death rates are, in some cases, highest and increasing at a faster rate among Black people compared to other racial/ethnic groups. This secondary analysis study investigated treatment preference, retention, and relapse rates amongst a subgroup of 73 Black participants with OUD (81% male, mean age 39.05, SD = 11.80) participating in a 24-week multisite randomized clinical trial ("X:BOT") comparing the effectiveness of extended-release naltrexone (XR-NTX) and sublingual buprenorphine-naloxone (BUP-NX) between 2014–2017. Chi-square analyses were used to investigate treatment preference assessed at baseline, and logistic regression analyses were used to investigate differences in the odds of retention and relapse assessed over the 24-week course of treatment between treatment groups. Our findings suggest no differences in preference for XR-NTX versus BUP-NX. However, similar to the parent trial, there was an induction hurdle such that only 59.5% of those randomized to XR-NTX successfully initiated medication compared to 91.6% of those randomized to BUP-

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Contributors All authors contributed to the conceptualization of the project with Dr. Haeny taking lead on the project. Drs. Haeny, Montgomery, Burlew, and Campbell developed the original draft of the manuscript. Ms. Scodes took lead on the analyses and data management. Drs. Rotrosen and Nunes were involved in the original clinical trial, and all authors contributed to writing, reviewing, editing, and approving the final version of the manuscript.

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NX (OR=0.13, 95% CI=0.04, 0.52). No significant differences were found in treatment retention (intention-to-treat: OR=1.19, 95% CI=0.43, 3.28; per-protocol [i.e., those who initiated medication]: OR=0.60, 95% CI=0.20, 1.82) or relapse rates between treatment groups (intention-to-treat: OR=1.53, 95% CI=0.57, 4.13; per-protocol: OR=0.69, 95% CI=0.23, 2.06). Although there is a significant initiation hurdle with XR-NTX, once inducted, both medications appear similar in effectiveness, but as in the main study, dropout rates were high. Future research is needed on how to improve adherence.

Keywords

Black/African American; opioid use disorder; Buprenorphine; Naltrexone

Introduction

The increasing misuse of opioids has resulted in a stark increase in drug overdose deaths (Blanco & Volkow, 2019; Spencer et al., 2019). Although the opioid epidemic has been largely conceptualized as a White problem, deaths due to opioid overdose are highest among Black people in multiple states (Bechteler & Kane-Willis, 2017; James & Jordan, 2018). Recent reports also indicate that overdose deaths due to fentanyl are increasing at a higher rate among Black relative to White and Latinx people (Spencer et al., 2019). In addition, emergency room visits due to prescription opioid use increased 255% among Black people between 2004–2011 (Center for Behavioral Health and Statistics, 2013) and treatment admissions for primary heroin and prescription opioid use has increased 10% and 44%, respectively, among older Black adults (Huhn, Strain, Tompkins, & Dunn, 2018). Despite these data, less is known about effective treatments for opioid use disorder (OUD) among Black people (Montgomery, Burlew, Haeny et al., 2019; Peteet, 2019) beyond descriptive epidemiological data (Blanco & Volkow, 2019).

Extended-release naltrexone (XR-NTX), an opioid antagonist, and sublingual buprenorphine-naloxone (BUP-NX), a partial opioid agonist, are two efficacious treatments for OUD (Blanco & Volkow, 2019; Krupitsky et al., 2011; Lee et al., 2016; Mattick, Breen, Kimber, & Davoli, 2009; Mattick, Kimber, Breen, & Davoli, 2004). Although moderation by race or subgroup analyses were not reported, studies that include Black participants provide evidence of the efficacy of XR-NTX, buprenorphine, and methadone in improving OUD outcomes (e.g., 29% Black: Fudala et al., 2003; 30% Black: Gruber, Delucchi, Kielstein, & Batki, 2008; 50% Black: Lee, Friedmann, et al., 2016). In addition, recent research provides evidence of the efficacy of BUP-NX among Black adults with OUD (Monico et al., 2018). However, no study has examined preference for XR-NTX versus BUP-NX among Black adults.

The induction hurdle associated with XR-NTX (well-explicated elsewhere: Lee et al., 2018) is an important distinction from BUP-NX. Specifically, XR-NTX cannot be initiated until an individual is fully detoxified. Findings from a randomized comparative effectiveness trial conducted within NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), referred to as X:BOT, found successful induction was higher among BUP-NX than XR-NTX

(Lee et al., 2018). Among those randomly assigned (i.e., intention-to-treat), the BUP-NX group had fewer relapses than the XR-NTX group (attributable to the lower induction rate); however, once successfully inducted onto XR-NTX or BUP-NX (i.e., per-protocol), the medications were similarly effective. These findings were for the overall sample, which was 74% White; subgroup analyses by race have not yet been reported. Thus, the objectives of the present study were to compare XR-NTX and BUP-NX on treatment preference, retention, and relapse rates among Black adults in X:BOT.

Methods

Participants

X:BOT was a 24-week open-label comparative effectiveness trial of 570 participants (across 8 inpatient detoxification sites) randomized to either XR-NTX and sublingual BUP-NX (see Lee, Nunes, et al., 2016; Lee et al., 2018; Nunes et al., 2016 for detailed study information). Participants were (1) 18 years of age or older, (2) spoke English, (3) had Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5: American Psychiatric Association, 2013) OUD, (4) had used non-prescribed opioids in the past 30 days, and (5) had no other serious medical, psychiatric or substance use disorders. X:BOT consisted of 570 participants, 474 of whom were successfully inducted onto one of the study medications (Lee et al., 2018). We decided against conducting race comparisons between Black and non-Black participants in X:BOT because: 1) such designs may disregard the possibility that race may be a proxy for other socio-demographic differences (e.g., socioeconomic status, barriers to treatment), 2) what may appear to be race differences may actually be attributable to contextual factors in site selection (public vs private clinics), and 3) these designs often ignore the influence of measurement non-equivalence. (See Burlew, Feaster, Brecht, & Hubbard, 2009; Burlew, Peteet, McCuistian, & Miller-Roenigk, 2019a; Burlew et al., 2011 for limitations of race comparisons.) The current study is a secondary analysis of the Black subsample (Intention-to-treat subsample: $N=73$; Per-protocol subsample: $N=55$). All sites obtained local Institutional Review Board Approval and participants provided informed consent, which included information on each study medication.

Measures

Research visits occurred weekly for the first month, then biweekly (week 6 and 8), and monthly (week 12, 16, 20, and 24) and included assessments of demographic, medical, psychiatric (e.g., Hamilton Depression Scale; Bagby et al., 2004), drug use and treatment history, opioid withdrawal symptoms (Subjective Opioid Withdrawal Scale [SOWS]; Gossop, 1990), treatment preference, quality of life and current health status, in addition to blood and urine testing. Race was determined based on self-report. Participants who self-identified as Black regardless of whether they endorsed any other race or ethnicity were categorized as Black. For the treatment preference measures, before randomization, participants were separately asked to state on a scale from 1 to 5 (1=Strongly Disagree; 5=Strongly Agree) if they would prefer to receive BUP-NX or XR-NTX. The primary outcome measure was relapse (binary: yes/no) during the 24-week trial. Relapse was operationalized as four consecutive opioid use weeks as determined by self-report and/or urine toxicology or seven consecutive days of use as measured by the Timeline Follow-Back

(Sobell and Sobell, 1992), starting from day 21 postrandomization. Missing urine samples were coded as positive. Those who discontinued study medications early were categorized as treatment non-completers.

Procedures

All participants were randomized while in detoxification settings or short term residential settings using a centralized, automated block assignment stratified by treatment site and opioid use severity (high severity was 6 bags or equivalent intravenous heroin per day in the 7 days before admission). Following randomization, participants were inducted as quickly as possible onto study medication. Participants also received medical management (e.g., medication adherence, promotion of psychosocial treatment) at each study visit. All research visits took place in a treatment setting (inpatient initially and then in the community). XR-NTX and BUP-NX were discontinued following a relapse event, at the end of 24 weeks, or per safety concerns or participant preference. Participants were encouraged to extend treatment with buprenorphine, methadone, or naltrexone after the study.

Data Analysis Plan

As in X:BOT (Lee et al., 2018), analyses were conducted for both the intention-to-treat and per-protocol participants. Demographic and treatment preference comparisons across treatment group were analyzed using chi-square tests for categorical measures, t-tests for normally distributed continuous measures, and non-parametric Wilcoxon rank test for skewed continuous measures. Logistic regression was used to estimate odds of treatment completion and relapse among those receiving XR-NTX vs. BUP-NX in SAS® version 9.4 (SAS Institute Inc.). We also estimated median time to relapse for each treatment.

Results

Sample Demographics

Most of the Black subsample ($N=73$) of X:BOT was male, non-Hispanic, single, unemployed, primary heroin users, with a mean age of 39.05 (SD=11.80) years. Of those randomized to XR-NTX ($n=37$), 22 (59.5%) were successfully inducted onto medication compared to those randomized to BUP-NX ($n=36$) of which 33 (91.6%) were successfully inducted (OR=0.13, 95% CI=0.04, 0.52). Characteristics of the intention-to-treat and per-protocol sample were similar (Table 1).

Treatment Preference

Table 1 includes treatment preference descriptive summaries. Although a slightly higher percentage of participants reported preference for the treatment they were randomized to, there was no significant difference in treatment preference by treatment group. This was true for the per-protocol sample as well. In addition, there was no difference in relapse rates between XR-NTX and BUP-NX among those randomized to their treatment of choice (Supplementary Table 1).

Treatment Outcomes

The odds of treatment completion and relapse were examined by treatment group in both the intention-to-treat and per-protocol samples. No difference in the odds of treatment completion by medication type was found in the intention-to-treat (OR=1.19, 95% CI=0.43, 3.28) or the per-protocol samples (OR=0.60, 95% CI=0.20, 1.82). Similarly, no significant difference in the odds of relapse between groups (XR-NTX vs. BUP-NX) was found in the intention-to-treat (percent relapsed: 73.0% vs. 63.9%; OR=1.53, 95% CI=0.57, 4.13) or the per-protocol samples (percent relapsed: 54.5% vs. 63.6%; OR=0.69, 95% CI=0.23, 2.06). The rates of relapse by treatment group are provided in Table 2. In addition, those randomized to XR-NTX (3.14 weeks, interquartile range [IQR]=3.00, 24.00) had a shorter median time to relapse compared to those on BUP-NX (10.43 weeks, IQR=3.29, 24.00) in the intention-to-treat sample. However, among the per-protocol sample, the median time to relapse was similar for those randomized to XR-NTX (8.43 weeks, IQR=3.00, 24.00) compared to BUP-NX (8.43 weeks, IQR=3.29, 24.00).

Discussion

Given limited research on effective treatments for OUD among Black people, the present study sought to address this gap by investigating the effectiveness of BUP-NX versus XR-NTX on opioid treatment preference, retention, and relapse among Black adults. In the parent trial (Lee et al., 2018), BUP-NX had lower odds of relapse in the intention-to-treat sample, and the findings in the current sample show a comparable trend. In both the parent trial and the current analysis, the rate of relapse is lower among those in the per-protocol sample who received XR-NTX compared to BUP-NX; however, the difference is much larger in the Black subsample though not statistically different. A similar induction hurdle was found in the parent study and the current study; however, an even lower proportion of participants were inducted onto XR-NTX in the current sub-sample of Black participants (59.5%) compared to the overall sample (72.1%). These findings highlight a need to find strategies for overcoming the XR-NTX induction hurdle overall but especially for Black adults. Alternatively, these findings may also leave clinicians to believe BUP-NX is the optimal pharmacotherapy for OUD because there is less of an induction hurdle. Given that the findings from this study indicated no difference in the preference or effectiveness of BUP-NX and XR-NTX for Black participants once inducted, prescribers may inform patients of the pros and cons of each medication and select which treatment to use based on shared decision-making with the patient.

The findings from this study should be considered in the context of its limitations. The sample size of Black participants was relatively small, and our analyses were likely underpowered to detect effects especially given that the parent study did not aim to recruit a representative sample of Black participants in each treatment condition to investigate race differences. Limitations of conducting subgroup analyses and lumping Black people who identify as more than one race together is further perpetuating the assumption that the subgroup is a monolith and not accounting for pertinent within group differences (e.g., sex, ethnic identity, religiosity) that may impact treatment outcomes.

In summary, these findings highlight the importance of identifying strategies for improving induction on XR-NTX (e.g., Bisaga et al., 2018; Sigmon et al., 2012) and investigating potential inequity issues that might contribute to a higher induction hurdle among Black people with OUD like limited access to inpatient treatment or differences in symptom management during induction. Conducting moderator or, in this case, subgroup analyses allows for a clearer understanding of preference for and effectiveness of medications in reducing dropout and relapse among Black people with OUD without assuming the findings based on the overall sample generalize to all racial/ethnic groups. Additional research is needed to identify approaches to reduce relapse for both treatments. Given recent studies have highlighted important factors associated with treatment outcomes specifically among Black patients with OUD, such as the association between alcohol and cocaine use and non-adherence to BUP-NX treatment (Kumari et al., 2016) and the link between baseline treatment characteristics (e.g., use of other substances, sibling and parent substance use history) and poor methadone maintenance treatment outcomes (Lister, Greenwald, & Ledgerwood, 2017), future studies should replicate these findings using a larger sample accounting for these and other within group variables (e.g., sex, socioeconomic status, age). Additional studies are also warranted to identify whether other moderator variables (e.g., outpatient vs. residential treatment, co-occurring psychopathology, polysubstance use) and barriers including treatment access and affordability affect both successful induction and relapse rates. Finally, these findings contribute to closing the gap in the larger literature by providing insight on efficacious medication treatments for Black people with substance use disorders, an area in need of further research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Compared extended-release naltrexone and buprenorphine naloxone in Blacks with OUD
- There was a high induction hurdle for those randomized to extended-release naltrexone
- No difference in preference or relapse rates was found between the two medications
- Findings suggest both medications are efficacious treatments for OUD among Blacks
- Replication is needed in a larger sample of Blacks with OUD

Table 1. Demographic and clinical measures by treatment for all intention-to-treat (N=73) and per-protocol (n=55) Black participants

Demographic and Clinical Measures	Intent to Treat Sample (N=73)			Per Protocol Sample (N=55)		
	N	% or Mean (SD)	Buprenorphine (N=36)	Naltrexone (N=22)	Buprenorphine (N=33)	Naltrexone (N=22)
Gender (% male)	29	78.4%	30	83.3%	18	81.8%
Age	37	40.2 (11.3)	36	37.9 (12.3)	22	41.0 (11.0)
Hispanic Ethnicity (% Hispanic)	3	8.1%	3	8.3%	0	0.0%
Marital Status						
Have been married	8	21.6%	13	36.1%	4	18.2%
Never Married	29	78.4%	22	61.1%	18	81.8%
Unknown	0	0.0%	1	2.8%	0	0.0%
Employment (% Not Employed)	29	78.4%	21	58.3%	15	68.2%
IV Use (% yes)	17	45.9%	17	47.2%	10	45.5%
Primary Opioid (7 days prior to adm)						
Buprenorphine	1	2.7%	0	0.0%	0	0.0%
Opioid analgesics	4	10.8%	3	8.3%	3	13.6%
Heroin	32	86.5%	33	91.7%	19	86.4%
Primary Opioid Cost (\$/day)	37	76.3 (61.8)	36	86.8 (53.6)	22	80.4 (67.8)
Age at onset of opioid use ^a	37	22.8 (6.3)	36	24.6 (9.8)	22	23.0 (5.9)
Duration of Opioid Use (years)	37	17.4 (12.6)	36	13.3 (11.0)	22	18.0 (13.1)
First Treatment Episode (% yes)	16	43.2%	17	47.2%	9	40.9%
Stimulant use (30d prior to adm) (% yes)	16	43.2%	23	63.9%	9	40.9%
Sedative use (30d prior to adm) (% yes)	6	16.2%	10	27.8%	4	18.2%
Heavy Alcohol use (30d prior to adm) (% yes)	9	24.3%	7	19.4%	7	36.4%
Cannabis use (30d prior to adm) (% yes)	14	37.8%	14	38.9%	5	27.3%
HAM-D Score (Range: 0–52)	37	7.6 (5.9)	36	8.1 (6.2)	22	7.9 (5.7)
Any Psych Disorders (% yes)	17	45.9%	15	41.7%	9	40.9%
SOWS (Median/IQR) (Range: 0–64)	37	7.0 (1.0–16.0)	36	9.0 (4.0–22.0)	22	3.0 (1.0–11.0)
Treatment Preference Measures						
Preference: Buprenorphine						

Demographic and Clinical Measures	Intent to Treat Sample (N=73)				Per Protocol Sample (N=55)			
	Naltrexone (N=37)		Buprenorphine (N=36)		Naltrexone (N=22)		Buprenorphine (N=33)	
	N	% or Mean (SD)	N	% or Mean (SD)	N	% or Mean (SD)	N	% or Mean (SD)
Disagree/Strongly Disagree	10	27.0%	6	16.7%	6	27.3%	5	15.2%
Neutral	16	43.2%	17	47.2%	10	45.5%	15	45.5%
Agree/Strongly Agree	11	29.7%	13	36.1%	6	27.3%	13	39.4%
Preference: Naltrexone								
Disagree/Strongly Disagree	7	18.9%	6	16.7%	5	22.7%	5	15.2%
Neutral	17	45.9%	21	58.3%	10	45.5%	20	60.6%
Agree/Strongly Agree	13	35.1%	9	25.0%	7	31.8%	8	24.2%

^aIncludes: heroin, methadone (prescribed or illicit), and opioid analgesics, d = days, adm = admission.

Note. 30d = 30 days. Adm = admission.

Table 2.

Opioid treatment outcomes

	Naltrexone (n = 37)	Buprenorphine (n = 36)	Treatment Effect
Induction to study medication			
Intention-to-treat group	22 (59.5%)	33 (91.6%)	OR: 0.13, 95% CI: 0.04, 0.52
Opioid Relapse			
Intention-to-treat (n=73)	27 (73.0%)	23 (63.9%)	OR: 1.53, 95% CI: 0.57, 4.13
Per-Protocol (n=55)	12/22 (54.5%)	21/33 (63.6%)	OR: 0.69, 95% CI: 0.23, 2.06

Note. Findings reported as n (%). OR = odds ratio. 95% CI = 95% confidence interval.