International Journal of Drug Policy 24 (2013) e91–e98

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Research paper

Methadone treatment improves tuberculosis treatment among hospitalized opioid dependent patients in Ukraine

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ARTICLE INFO

Article history:
Received 6 April 2013
Received in revised form 19 July 2013
Accepted 2 September 2013

Keywords:
Methadone maintenance
Tuberculosis
HIV/AIDS
MDR-TB
Treatment retention
Adherence
Substance Abuse
Opioid dependence
Ukraine

ABSTRACT

Background: Ukraine's volatile syndemics of tuberculosis (TB) and HIV among people who inject drugs (PWIDs) introduces numerous treatment challenges for each condition, including high mortality and development of multi-drug resistant TB (MDR-TB).
Methods: A prospective, non-randomized 90-day observational study was conducted in six Ukrainian TB treatment sites to assess the effectiveness of integrating methadone maintenance (MMT) with TB treatment using: (1) 90-day TB treatment retention; (2) time to treatment discontinuation; (3) TB medication adherence; and (4) subject disposition, including mortality. Of the 110 participants enrolled, 57 received MMT and 53 did not (non-MMT).
Results: All of the primary outcomes were significantly better in MMT versus non-MMT groups, including 90-day TB treatment completion (89.5% versus 73.6%; $p = 0.031$), time to TB treatment discontinuation ($p = 0.039$) and TB medication adherence (97.1% versus 86.2%; $p < 0.001$) after controlling for death. The major reasons for treatment non-completion in the non-MMT group included death ($N = 3$), administrative discharge from the clinic ($N = 5$), loss to follow-up ($N = 2$), and arrest ($N = 4$). Overall, 90-day mortality was high (8.2%). After controlling for covariates differing between the two groups at baseline, the only independent predictor of completing 90 days of TB treatment was receipt of MMT in an integrated treatment setting (AOR = 3.05; 95% CI 1.08–8.66).
Conclusions: MMT integrated into inpatient TB treatment significantly improves retention in TB treatment and TB medication adherence among PWIDs. These findings call for policy change to increase the number of MMT sites in TB facilities and make MMT a low-threshold treatment option for opioid dependence in Ukraine.

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Background

With nearly 2 billion people infected worldwide (Glaziou, Floyd, & Raviglione, 2009), tuberculosis (TB) remains a major global public health problem and contributes significantly to morbidity and mortality. In 2010, there were 8.8 million incident TB cases, of which there were 1.1 million TB-related deaths among people not infected with HIV. Co-infection with HIV and TB, however, creates challenges in both diagnosis and treatment, thus contributing to worse treatment outcomes and mortality rates exceeding 13%. Globally, the absolute annual number of incident TB cases has continued to decrease since 2006, with incidence decreasing by 1.3% annually since 2002. Though these findings are seen across all six global reporting regions, there has been little improvement in these findings in many countries of the former Soviet Union (FSU), including Eastern Europe and Central Asia – a region where both HIV and TB are high among drug using populations and MDR-TB is expanding (World Health Organization, 2011).

People who inject drugs (PWIDs) remain at high risk for tuberculosis (TB), including in low-, middle- and high-income countries. As a result, the twin epidemics of drug use and TB coexist in a number of countries globally. Treatment of TB among PWIDs poses a unique set of challenges for TB diagnosis and control efforts. In recognition of this special relationship the World Health Organization, the Joint United Nations Programme on HIV/AIDS, and the United Nations Office on Drugs and Crime, released guidelines to improve coordinated care for TB among PWIDs (World Health Organization, 2008). Among the recommendations is to integrate TB treatment with medication-assisted therapy for opioid dependence, and if indicated, with HIV treatment services (Sylla, Bruce, Kamarulzaman, & Altice, 2007; World Health Organization, 2008).

Ukraine, a country facing multiple challenges in the context of volatile epidemics of TB and HIV among PWIDs, faces a number of

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http://dx.doi.org/10.1016/j.drugpo.2013.09.001

important challenges in optimizing treatment outcomes for each condition, including the development of multi-drug resistant TB (MDR-TB) (Dubrovina et al., 2008; Granich, 2008; Hurley, 2010; Kruglov et al., 2008; Kruk et al., 2011; Wolfe, Carrieri, & Shepard, 2010). Though Ukrainian MDR-TB rates are not fully known, one regional study conducted in 2006 identified a range from 15.5% to 41.5% among newly identified and previously treated TB cases in community settings, respectively (Dubrovina et al., 2008). HIV prevalence among PWIDs in Ukraine is estimated to be 21.5% (Ministry of Health of Ukraine, 2012), while TB prevalence data among PWIDs in Ukraine are currently not available, since no comprehensive assessment has been done. Nonetheless, PWIDs remain at high risk of developing active TB, especially in settings with high HIV and TB prevalence (Deiss, Rodwell, & Garfein, 2009; Getahun, Gunneberg, Sculier, Verster, & Raviglione, 2012). Officially reported TB case notification rate in Ukraine, likely an under-representation of the true epidemic, was 74 per 100,000 population in 2010 – more than twice the average rate for the European region that same year (World Health Organization, 2011). Though multiple factors contribute to the development of MDR-TB among PWIDs, poor adherence to therapy and discontinuation of treatment may all contribute to poor outcomes and such factors have been described as consequences of the lifestyle patterns of PWIDs, including the need to procure drugs on daily basis (Pablos-Mendez, Knirsch, Barr, Lerner, & Frieden, 1997; Story, Murad, Roberts, Verheyen, & Hayward, 2007).

In recognition that opioid dependence is a chronic, relapsing condition, this study compared the concomitant treatment of TB and opioid dependence using MMT, an evidence-based pharmacological treatment for opioid dependence, with TB patients not receiving MMT. To describe and understand better how to optimally organize TB treatment among PWIDs in Ukraine, the research compared 90-day treatment completion, time to TB treatment discontinuation, TB medication adherence and treatment disposition (including death) among hospitalized pulmonary TB patients with co-morbid opioid dependence being treated in an integrated care setting.

Methods

Study sites

A 90-day observational study was conducted in six TB treatment sites in Ukraine between December 2011 and April 2012. Directly observed therapy (DOT) is required for all TB patients in Ukraine according to the Ministry of Health guidelines. Unlike in other countries, the Ukrainian guidelines allow for TB patients who are deemed “unstable” (homeless, active drug users, previous treatment defaulters, etc.) or who have MDR-TB to be forcibly “hospitalized” for prolonged periods of time to reduce risk of transmission to others. This approach is the standard of care and common in most FSU countries. Medication acceptance and adherence, however, remains voluntary but is a condition for community release. As part of Ukraine’s new efforts to expand MMT throughout the country, it was made available in some TB hospital sites. MMT sites in Mykolayiv, Odesa and Kherson were selected because of the availability of comprehensive and integrated care sites that included the additional provision of MMT for hospitalized pulmonary TB patients. The comparison group was recruited from TB treatment hospitals in Kyiv, Donetsk, and Dnipropetrovsk where MMT was not provided within TB treatment settings. The standard of care includes consultation with a drug addiction specialist, if agreed by the TB doctor, and detoxification is prescribed by the doctor if indicated and agreed upon by the patient.

Study participants

A total of 110 participants were enrolled and prospectively followed for 90 days: $N = 57$ in the study (MMT) group and $N = 53$ in the comparison (non-MMT) group. All study participants met the following inclusion criteria: (1) were ≥18 years; (2) met ICD-10 criteria for opioid dependence (Janca, Ustun, Early, & Sartorius, 1993); (3) had confirmed pulmonary TB diagnosis; (4) were prescribed at least 90 days of inpatient TB treatment from baseline enrolment; and (5) provided written informed consent. The fourth criterion was established in order to standardize outcome measurement, given that the TB status of patients may differ based on factors such as new or repeated treatment, different levels of underlying drug resistance, and duration and severity of TB disease which were not fully measured in this study.

Our final analytical sample compared those who were prescribed MMT with those who were not. No minimum MMT dose was required for study entry and dose varied considerably. All MMT was initiated at the time of pulmonary TB diagnosis in the integrated care site. Eight study participants in Odessa, Mykolayiv and Kherson, however, were ultimately analysed in the non-MMT group because they either refused MMT or did not meet legally established eligibility criteria for MMT enrolment in Ukraine (at least two previous documented unsuccessful treatment attempts using behavioural counselling). Assigning them to MMT would have incorrectly examined the impact of MMT (which they never received) and removing them from the analysis did not alter the final outcomes. All individuals enrolled in the study were assigned an anonymous code, which was linked with the data collection instruments. Participants were paid 80 UAH (~$10 USD, 2012 exchange rate) for completion of interviews.

Data collection

Data were collected at baseline and throughout 90 days of observation. Baseline interviews included patient demographic and social characteristics, drug and alcohol use, psychiatric conditions, previous HIV testing and current status, prescription of antiretroviral therapy (ART), previous TB treatment history and attitudes toward TB treatment (both groups) and MMT (MMT group only). Drug use portions were adapted from the Addiction Severity Index (ASI-lite), modified to include local Ukrainian drug use (McLellan, Luborsky, Woody, & O’Brien, 1980).

Chart reviews after 90 days recorded HIV testing, ART prescription, DOT record of taking observed TB and methadone medications, and reasons for treatment discontinuation (recorded by the TB doctor). Adverse side effects were not systematically recorded or obtained.

The TB treatment outcomes (dependent variables) included: (1) percentage of patients completing 90 days of TB treatment and continuing with treatment at the end of the study; (2) time to discontinuation of TB treatment; (3) percentage of dosage of TB medications taken over the 90 days of observation; and (4) disposition of study participants, including death and the reasons for drop-out. For the purpose of this study, treatment discontinuation was defined as not receiving TB medications for two weeks or more. For time-based measurements, the date of the last dose of TB medication taken was used for the date of treatment discontinuation.

Data analysis

Statistical analyses were performed using SPSS software for Windows (version 19.0, Chicago, IL). Characteristics of study subjects were mostly analysed as categorical variables, and collapsed where frequencies were small. Age, duration of drug use, number of TB medications prescribed, and number of days of hospitalization in

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