A Clinical Study of Opioid Substitution Therapy in a Tertiary Care Center of Eastern India

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ABSTRACT

Background: Opioid substitution therapy (OST) is an evidence-based intervention for opiate-dependent persons that replaces illicit drug use with medically prescribed, orally administered opiates such as buprenorphine and methadone. OST reduces HIV risk behaviors and harms associated with injecting opioid. Most of the evidence for OST effectiveness has been generated in middle- and high-income countries where programs are mostly located in dedicated health-care settings; evidence regarding the outcomes of OST programs in low-income countries where OST is often provided in grassroots settings such as drop-in centers is limited. Aims and Objectives: To study the sociodemographic variables, HIV ELISA status, HIV risk behavior, comorbid substance use pattern, and required dose of buprenorphine used for treatment of injection drug users (IDUs) attending oral substitution therapy (OST) center at a tertiary health care center. Methodology: A total of IDUs aged 18–60 years who attended the OST center during 1-year period at a government medical college are included in the study. Results: Majority of the IDUs are male with mean age of 32.8 years. The mean dose of buprenorphine used for the substitution was 4.6 mg/day at the start of therapy. Most of the IDUs are of lower educational status and educated up to primary or middle school. 32.50% of the participants who are unemployed are totally dependent on the family. Most common substance abuse among IDU users were tobacco (74.17%), followed by heroine (57.5%). High-risk behavior found among OST clients was unprotected sexual intercourse (19.17%), sharing needle (11.67%), and sexual intercourse with multiple partners (6.67%). HIV ELISA testing showed positive among 2 (1.67%). Conclusion: These findings have relevance to other parts of India and Asia, where injecting drug use is common and is a first step toward filling the gap in knowledge regarding the effectiveness of community-based OST programs delivered in resource-constrained settings.

Key words: Eastern India, injection drug users, opioid substitution therapy

INTRODUCTION

Opioid substitution therapy (OST) is an evidence-based intervention for opiate-dependent persons that replaces illicit drug use with medically prescribed, orally administered opiates such as buprenorphine and methadone. OST reduces HIV risk behaviors and harms associated with injecting opioid.
associated with injecting (such as abscesses, septicemia, and endocarditis), overdose, and participation in criminal activity, thereby improving the quality of life and health of injecting drug users (IDUs).\textsuperscript{[1,2]} It is endorsed by UNAIDS, UNODC, and WHO as part of a comprehensive package of nine core interventions for IDU programs that collectively maximize impact for HIV prevention and treatment.\textsuperscript{[3]} However, most of the evidence for OST effectiveness has been generated in middle- and high-income countries, where programs are mostly located in dedicated healthcare settings; evidence regarding the outcomes of OST programs in low-income countries where OST is often provided in grassroots settings such as drop-in centers is limited.\textsuperscript{[4]} Opioid use disorders are a significant public health problem in South Asia and in particular, India. According to the World Drug Report 2010, there are 871,000 heroin and 674,000 opium users in India.\textsuperscript{[5]} The National Household Survey data from India showed that the prevalence of current opioid use in the general population was 0.7\%.\textsuperscript{[6]} A significant proportion (26\%) of treatment seekers at deaddiction centers in India reported opioid as the primary drug of abuse.\textsuperscript{[7]} Only 5\% of opioid drug users are currently receiving OST, which is mostly delivered by community-based services.\textsuperscript{[8,9]} There is a real need for evidence regarding outcomes of OST provision in India, to strengthen the case for scaling up of services.

In view of the dearth of studies from Eastern India on the usefulness of OST, we planned to study the sociodemographic variables, HIV ELISA status, HIV risk behavior, comorbid substance use pattern, and required dose of buprenorphine used for the treatment of injection drug users (IDUs) attending oral substitution therapy (OST) center at a tertiary health care center.

**METHODOLOGY**

This cross-sectional study was conducted among all the new IDUs of age >18 years and <60 years of age, of either sex attending the opioid substitution therapy (OST) center at Mental Health Institute, Department of Psychiatry, SCB Medical College, Cuttack, Odisha, for 1-year period from December 2015 to November 2016 and have injected drugs at least once in the past 3 months have been included in the study after taking written informed consent. Each IDU is interviewed in detail by separate questionnaires regarding sociodemographic parameters, pattern, type, and frequency of drug used in injection, HIV risk behaviors, and comorbid substance use types.

**Inclusion criteria**

Age 18–60 years, those IDUs of 1-year duration, current IDUs (who have injected drugs at least once in the last 3 months), those giving consent to participate were included in the study.

**Exclusion criteria**

Pregnant and lactating women of age <18 and >60 years were excluded from the study.

**Ethical clearance**

The study was approved by the Ethical Committee.

This study involves analysis of data collected routinely during the implementation of an OST program.

**RESULTS**

The total number of cases registered within the study period for opioid dependence syndrome was 120. Out of them, 118 (98.33\%) were men and 2 (1.67\%) were women. The mean age of the sample was 32.8 years. The mean dose of buprenorphine used for the substitution was 4.6 mg/day at the start of therapy.

As shown in Table 1, most of the IDUs are of lower educational status and educated up to primary or middle school. Nearly 32.50\% of the participants who are unemployed are totally dependent on the family and friends for their financial expenses related to drug use and other chores. 54\% of the participants are using injection drug for the last 4–6 years with mean duration use of 3.2 ± 2.8 years. Most (55.84\%) of the patients were

| Table 1: Opioid substitution therapy client sociodemographic characteristics at intake (n=120) |
|-----------------------------------------------|
| **Demographic characteristic** | **n (%)** |
|-----------------------------------------------|
| Sex | Male 118 (98.33)  |
| | Female 2 (1.67)  |
| Marital status | Married 48 (40.00)  |
| | Single 65 (54.17)  |
| | Separated/divorced 5 (4.17)  |
| | Widowed 2 (1.66)  |
| Education | No education 5 (4.17)  |
| | Primary school 80 (66.66)  |
| | High school 8 (6.67)  |
| | Undergraduate 15 (12.50)  |
| | Graduate and above 12 (10.00)  |
| Occupation | Unemployed 39 (32.50)  |
| | Employed 81 (67.50)  |
| Source of referral | Friend/peer 67 (55.84)  |
| | Family 4 (3.33)  |
| | Peer educator 4 (3.33)  |
| | Outreach worker 39 (32.50)  |
| | Other 6 (5.00)  |
were unprotected sexual intercourse (19.17%), sharing needle (11.67%), and sexual intercourse with multiple partners (6.67%) [Table 3]. HIV ELISA testing showed positive among 2 (1.67%) [Table 4].

**DISCUSSION**

In our study, the mean age of the sample was 32.8 years and one quarter (26) aged 45 or older. About 40% of our participants are married, rest are unmarried, divorced, or separated. A study by Sarin et al.\textsuperscript{[15]} on 449 IDUs in New Delhi shows that 35% of the participants were married, but only 26% lived with their spouses and rest were separated. Another study by Kermode et al.\textsuperscript{[12]} on IDUs in Nagaland shows that 66% were single and 34% were married. It might be because IDUs spent most of their time and money in drug use and are unable to fulfill their social responsibilities.

Most of the participants in our study are either illiterate or of lower educational status and only 30% of the participants have passed high school or above as shown in previous studies of Kermode et al.\textsuperscript{[12]} and Ambekar et al.\textsuperscript{[16]} Nearly 63.3% of the IDUs are unskilled worker and earn their livelihood mainly by rag picking and rickshaw driving. Sarin et al.\textsuperscript{[15]} Solomon et al.\textsuperscript{[17]} and Ambekar et al.\textsuperscript{[16]} show that rag picking is the main occupation of IDUs in India and only few have respectable jobs or business.

In our sample, the average dose of buprenorphine needed for maintenance was 4.6 mg less than the guidelines set (6–12 mg).\textsuperscript{[19]}

Given the poor support of OST in India, which is partly driven by prejudice toward drug users, poor understanding of the benefits of opioid substitution treatment, and reluctance to examine alternatives to behavioral treatments, we would commend these findings for greater professional and public discourse on OST in India.

These findings have relevance to other parts of India and Asia, where injecting drug use is common and is a first step toward filling the gap in knowledge regarding the effectiveness of community-based OST programs delivered in resource-constrained settings. A longitudinal prospective cohort study to systematically follow a cohort of OST clients over time would provide more rigorous evidence regarding outcomes, impact of different dosing schedules, social and economic benefits, program costs, and cost-effectiveness, and the extent to which clients are cycling in and out of the program. In addition, it would be useful to follow clients who cease treatment to compare the benefits of staying in treatment over those of leaving and to compare the effectiveness of community-based versus clinic-based OST delivery in similar resource-constrained settings.

OST can achieve similar outcomes consistently in a culturally diverse range of settings in low- and middle-income countries to those reported widely in high-income countries. It is associated with a substantial reduction in HIV exposure risk associated with IDU across nearly all the countries. Results support the expansion of opioid substitution treatment.

The treatment also helps improve the physical, psychological, and social well-being of the dependent users.

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**Table 2: Comorbid substance abuse\* among opioid substitution therapy clients (n=120)**

| Type of substance abuse | n (%) |
|-------------------------|-------|
| Heroin                  | 69 (57.5) |
| Alcohol                 | 34 (28.33) |
| Cannabis                | 54 (45.0) |
| Benzodiazepines         | 19 (15.830) |
| Tobacco                 | 89 (74.17) |

\*Not mutually exclusive

**Table 3: HIV risk behavior\* among opioid substitution therapy clients (n=120)**

| HIV risk behavior | n (%) |
|------------------|-------|
| Had shared a needle | 14 (11.67) |
| Had an unsafe sexual intercourse | 23 (19.17) |
| Sex with multiple partners | 8 (6.67) |
| Sex under the influence of alcohol or drugs | 6 (5) |

\*Not mutually exclusive

**Table 4: HIV ELISA status among opioid substitution therapy clients (n=120)**

| HIV ELISA status | n (%) |
|-----------------|-------|
| Positive        | 2 (1.67) |
| Negative        | 118 (98.33) |

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There is the need to conduct regular monitoring and evaluation of OST programs at national and local level.

**Limitations**
Clinic-based study population limits the generalizability of the outcome to the community. This study did not address other outcome variables such as number of lapses, quality of life of patient, and family.

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**Conflicts of interest**
There are no conflicts of interest.

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