

## Adherence to Buprenorphine Maintenance Treatment in Opioid Dependence Syndrome: A Case Control Study

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### ABSTRACT

**Background:** Opioid Use disorders are emerging as a serious public health concern in India. Opioid substitution treatment is one of the emerging forms of treatment in this population which needs more evidence to increase its availability and address prejudices towards the same. **Materials and Methods:** This is a case control study with retrospective design reviewing the charts of patients with opioid dependence syndrome registered between January 2005 to December 2012. Adherence to treatment was the outcome variable assessed in this study. **Results:** The odds of the Buprenorphine Maintenance Treatment (BMT) group remaining in treatment is 4.5 ( $P < 0.005$ ) times more than Naltrexone Maintenance Treatment (NMT) group and 7 times ( $P < 0.001$ ) more than Psychosocial intervention (PST) alone group. **Discussion:** We believe that these study findings will help in reducing the prejudice towards BMT and encourage further research in this field. **Conclusion:** BMT has a better adherence rate than other treatments in opioid use disorders.

**Key words:** *Buprenorphine maintenance treatment, naltrexone maintenance treatment, opioid substitution treatment, opioid dependence syndrome*


### INTRODUCTION

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.<sup>[1]</sup> The National Household Survey data from India showed that prevalence of current opioid use in the general population was 0.7%.<sup>[2]</sup> A significant proportion (26%) of treatment

seekers at deaddiction centres in India reported opioid as the primary drug of abuse.<sup>[3]</sup>

World over, there is a gradual paradigm shift in the management of opioid use disorder from symptomatic management and Naltrexone Maintenance Treatment (NMT) to opioid substitution therapy (OST) due to poor treatment retention with NMT.<sup>[4]</sup> Several studies have reported better outcome (retention in treatment, reduction of illicit drug use and reduction of craving) with Buprenorphine maintenance treatment (BMT).<sup>[4-9]</sup> But less than 2% of people who inject drugs in South-east Asia have access to OST.<sup>[10]</sup>

In view of the dearth of studies from south India on the usefulness of OST, we planned to study the effectiveness of BMT over NMT and Psychosocial Intervention alone as maintenance treatment.

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## MATERIALS AND METHODS

This study, designed as a case control study, was conducted at Centre for Addiction Medicine (CAM), National Institute of Mental Health And Neurosciences (NIMHANS), Bangalore. Case notes of all the patients who were seeking treatment for 'mental and behavioural disorders associated with Opioid use' (F11-ICD 10) from January 1, 2005 till December 31, 2012 were collected. The clinical data including the profile of opioids used, treatment received and the adherence to treatment were noted from the case notes.

The cases were divided into three groups as per the treatment received as BMT, NMT and PST in the form of symptomatic treatment with motivational interviewing and relapse prevention treatment). Outcome variable was studied as adherence to treatment at the 6<sup>th</sup> month and 1 year follow-up after the initiation of maintenance treatment. The study definition for adherence was regular follow-up under CAM and compliance to the medication prescribed. Compliance was ascertained by historical report of patient and it was confirmed with a significant other in the family and also by randomly checking the urine sample for opioids. Comparison was done for BMT and NMT with PST for the follow up rate by using Chi square, Odds ratio and Kaplan Meier survival analysis with help of Statistical Package for Social Sciences version 15 (SPSS 15).

## RESULTS

The total number of cases registered within the study period under CAM for opioid dependence syndrome was 248. Out of them 222 (89.5%) were men and 26 (10.5%) were women. The mean age of the sample was 30 ( $\pm 8.5$ ) years. 54 (22%) of the subjects used street opiate drugs and 201 (81%) used pharmaceutical opioids. Among this group, 181 (75%) cases were using opioids through oral and inhalation modes and 78 (31.45%) were injecting opioid users. The mean dose of Buprenorphine used for the substitution was 4.3 ( $\pm 2.3$ ) mg per day and Naltrexone was 50 mg per day.

The Kaplan Meier survival analysis [Figure 1] showed a significant difference between the three groups in follow-up at 6 months and 1 year ( $P < 0.001$ ). In the BMT group, the follow-up rate was 77% at 6 months and 68% at 1 year after initiation of treatment. In the NMT group, the follow-up rate was 57% at 6 month and 38% at 1 year after initiation of treatment. In the PST only group, the follow-up rate was 42% at 6 months and 25% at 1 year after initiation of treatment.

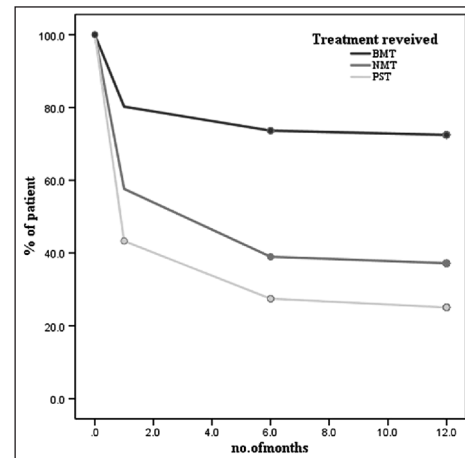


Figure 1: Follow up rate

Among all the cases at 1 year follow-up, the odds of BMT group remaining in treatment were seven times significantly ( $P < 0.001$ ) more than PST group, the odds of BMT group remaining in treatment were 4.5 times significantly ( $P < 0.005$ ) more than NMT group and the odds of NMT group remaining in treatment were 1.9 times more than PST group (non-significant). In the Intravenous Drug Users (IDU) group, at 1 year follow-up, the odds of BMT remaining in treatment were 10.8 times significantly ( $P < 0.001$ ) more than PST and the odds of NMT were not significant. Among the oral and inhalational users at 1 year follow-up, the odds of BMT group remaining in treatment were 6.7 times significantly ( $P < 0.001$ ) more than PST and the odds of NMT were 2.2 times significantly ( $P < 0.05$ ) more than PST.

## DISCUSSION

From this study it is evident that patients with opioid use disorder have significantly higher adherence to BMT than to NMT and PST. The reason for adherence could be due to a greater physical recovery and improvement in the quality of life.<sup>[11]</sup> As has been noted previously, this could be due to decrease in resting dopamine release in reward circuit in patients of opioid use disorders in patients on naltrexone.<sup>[12]</sup> In IDUs, BMT is again shown to be the most effective mode of management.

In our sample, the average dose of Buprenorphine needed for maintenance (4.3 mg) was less than the guidelines set (6-12 mg).<sup>[13]</sup> This could be due to a larger number of pharmaceutical opioid users in this particular sample. These results should argue for the strong move to increase the accessibility to buprenorphine treatment for management of opioid use disorder patients, with necessary safeguards to ensure compliance to treatment and prevent misuse.

The retrospective assessment of treatment retention is a limitation of this study. The study did not address other outcome variables like number of lapses, quality of life of patient and family etc. Clinic based study population limits the generalizability of the outcome to the community. Our searching the literature from the Indian sub-continent, this is the only study which had a study duration of outcome of patients over a period of 1 year. The results of this study clearly demonstrate the relative efficacy of Opioid Substitution treatment (BMT in Particular) in comparison to Naltrexone treatment and psychosocial treatment alone.

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

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