



Original Research Paper

Service User's Attitudes and Experiences Regarding Substitution Therapy with Buprenorphine

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Abstract

Introduction: No Indian study has explored attitudes and experiences of patients towards buprenorphine. The present study was done to assess the experiences and attitudes of buprenorphine users towards the drug.

Material and Methods: 200 adult males from opioid substitution therapy centers were cross-sectionally assessed. After taking written informed consent, socio-demographic and clinical performance, Attitudes towards Buprenorphine Questionnaire (translated in Punjabi) were applied. Appropriate statistical methods were used.

Results: Mean age of participants was 34.44 ± 10.113 years. Majority had less than 12 years of formal education (68%), were married (55.5%) and resided in joint families (69.5%) in urban locality (76%). Mean Attitudes towards buprenorphine questionnaire score was 100.69 ± 16.304 . Mean dose of buprenorphine was 6.38 ± 3.252 mg/day. More than 90% patients agreed that buprenorphine reduced craving, provides a normal life to an ex-addict and had done good for patients. However, 80% expressed that it should be stopped as early as possible. Nearly 40% believed that buprenorphine was an addiction, gives a high and difficult to stop. 80% patients endorsed that daily visits were problematic.

Conclusions: There is a huge gap between the number of patients who might benefit from buprenorphine and those who receive it. The positive attitudes and experiences of patients taking buprenorphine can be effectively used to bring out of treatment opioid addicts in the treatment system. Novel and diverse ways to deliver buprenorphine to suit the needs of majority of patient population are the need of the hour.

Keywords: Attitudes, Buprenorphine, Experiences, Opioid substitution therapy.

Introduction

Opioid substitution therapy (OST) with buprenorphine is effective in reducing illicit opiate use, high risk behaviors, death from overdose, criminal activity, and financial and other stressors on drug users and their families (Petersen et al., 2013). In India, OST is delivered through 2 different models: a non-governmental organizations (NGOs) run model and through OST centers situated in government hospitals. Evidence so far shows that these centers have high retention rates and improve psychosocial, physical health and overall quality of life (Rao et al., 2014). OST shows good acceptance by clients, their families and the community at large (Kumar et al., 2009). Despite all these positive developments, OST coverage remains abysmally low in India. World Health Organization targets were to enroll at least at least 40% (40000 out of a total of 177000 persons with injectable drug use in India) injectable drug users in OST program by 2012, through 320 sites. However, by 2014, only 150 OST centers in the country were catering to about 15000 regular users (Rao et al., 2014).

There are many challenges to scale up OST in India like high cost of buprenorphine, ineffective health services in some areas, lack of in depth knowledge about OST among policy makers, community members, drug users and health professionals, attitudes towards buprenorphine etc (Kermode et al., 2011; Reid et al., 2014). Ambivalent or negative attitudes toward buprenorphine may adversely affect enrolment and retention rates and outcomes (Liu et al., 2013; Schwartz et al., 2008). Few studies have examined attitudes towards and experiences with buprenorphine treatment among opioid users out of treatment or enrolling for therapy (Kelly et al., 2012; Schwartz et al., 2008). However, the experiences and attitudes of patients who are already enrolled in OST have not been adequately studied. The authors are not aware of any Indian study on attitudes towards and experiences with buprenorphine. Studies from elsewhere have shown that patients already enrolled in OST are

satisfied with treatment (Egan et al., 2011; Goulao, 2013). The present study was aimed to assess the experiences of and attitudes towards buprenorphine among patients who are already enrolled in OST.

Material and Methods

Study sample, design and settings: It was a cross sectional study conducted at OST centers of two tertiary care medical colleges. The centers have full-time staff consisting of a physician, a nurse, a counselor and a data manager. The NGO in charge of the targeted intervention in the vicinity of each center identifies and brings the clients for enrolment in the OST programme. Before enrolling the patients in the center, the consultant psychiatrist ensures that the patients fulfil ICD 10 criteria for opioid dependence and has been using injectable drugs. OST is a directly observed therapy and patients are required to visit the centers daily. The medicine is crushed and administered sublingually under direct supervision of the staff. Data was collected in June 2017. All the patients at OST centers were screened for inclusion and exclusion criteria. 100 patients were enrolled from each center using computer generated random numbers. The purpose and design of the study was explained to the participants, written informed consent for the study obtained and the rating instruments were applied by the researchers. The assessments were done at the OST centers. Approximately 30 – 40 minutes were spent for assessment of each patient.

Inclusion criteria

- i. Patient should have been taking buprenorphine from the OST center for at least 3 months and not taking any simultaneous treatment from any other place.
- ii. Age at least 18 years
- iii. No independent psychopathology (ruled out clinically and from case records file of patients at the OST centers).
- iv. Willing to give written informed consent for participation in the study.

Exclusion criteria: co-morbid psychiatric disorder, refusal to give written informed consent, patients not on buprenorphine, age less than 18 years.

Tools

Socio-demographic and clinical performa: a semi-structured performa was prepared to record socio-demographic and clinical variables including age, education, occupation, marital status, locality, family type, monthly income, current substance use (use during last 1 month), lifetime substance use (use for at least 1 year during the past), duration of buprenorphine use, dose of buprenorphine, duration between last injection and current assessment.

Attitudes towards buprenorphine questionnaire (Schwartz et al., 2008): The attitudes towards buprenorphine questionnaire was translated to Punjabi. It is a 28 item scale having good internal consistency. Each item is rated on a likert type scale from 1 – 5 (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree). Higher score on the individual items and the total scale means more positive attitudes. The negatively worded items are reverse scored. The items measure attitudes towards buprenorphine in terms of potential helpfulness, aid to behavior change, side effects, safety and efficacy of buprenorphine.

Study protocol

Translation of the scale

Written permission via email was obtained from the authors of the questionnaire to translate the instrument. 5 experienced psychiatrists well versed with both the languages translated the scale independently from English to Punjabi. The English and Punjabi versions made by consensus were then discussed with 2 experts of English to Punjabi translation to find out any discrepancy in the content and meaning of each item. Any discrepancy arising was removed with consensus. Both the versions were then administered on 20 patients (who could read and write both the languages) in ABAB paradigm and items were scored. Whenever 2 answers were not in

agreement, patient was interviewed to sort out the reasons for different responses when the content of items was same. There was 90 to 100% agreement in the responses of items and the mean agreement was 93%.

Ethical considerations

All the ethical guidelines were adhered to. The study was approved by the ethics committee of the institute. Written informed consent was taken from all the participants. The Indian Council of Medical Research ethical guidelines for biomedical research on human participants were adhered to. Patients were ensured that participation in the study was voluntary and would have no negative repercussions.

Statistical analysis

Analysis was conducted using IBM SPSS STATISTICS (version 22.0). Continuous data, (QOL and other variables) assumed to be normally distributed, was written as mean and standard deviation. When data was skewed, it was written in the form of median and inter quartile range, as per the requirement. Pearson correlation was used to calculate correlation between attitudes towards buprenorphine questionnaire with different variables. Cronbach's alpha was used to assess the reliability and internal consistency of the instrument. All the statistical tests were two-sided and were performed at a significance level of $\alpha=.05$.

Results

The attitudes to buprenorphine questionnaire was found to have good internal consistency (cronbach's alpha value 0.857). Mean age of the patients was 34.44 ± 10.113 years. Majority of the patients had less than 12 years of formal education (68%), were married (55.5%) and came from joint families (69.5%) in an urban locality (76%). The average monthly income of patients was 10037 ± 9571.342 INR.

The attitudes towards buprenorphine questionnaire score of 200 patients was 100.69 ± 16.304 . The duration between last injection and current

assessment was 21.99 ± 15.852 months. The duration of buprenorphine use was 26.07 ± 14.556 months. The mean dose of buprenorphine was 6.38 ± 3.252 mg/day. Out of 200 patients, 25 were HIV positive (12.5%).

Age was found to be significantly positively correlated with attitudes towards buprenorphine (correlation coefficient .238; significance 2-tailed .000^{***}). However, income had no significant correlation (correlation coefficient .092; significance 2-tailed .195). Duration of buprenorphine use was significantly negatively correlated with dose of buprenorphine (correlation coefficient $-.148$; sig. 2 tailed .037^{*}). Duration between last injection and assessment was significantly positively correlated with attitudes towards buprenorphine scale score (correlation coefficient .177; sig. 2 tailed .012^{*}).

Table 1 shows the correlation of attitudes towards buprenorphine with education, marital status, locality and family type. Patients having less than 12 years of formal education had significantly lower score as compared to those with higher education. Married persons had significantly higher score than single persons. Only 10% patients were unemployed at the time of conducting the study as compared to 20% prior to enrolment in OST.

Lifetime Substance use (for at least 1 year):

All the patients had used injectables in the past which is a necessary criteria for starting OST. More than 80% had used injectables for at least 1 year. Nearly 75% patients had used opioids in the past either before starting injections or along with it. 23% had used smack, 17% had used dextropropoxyphene, 12.5% bhukki, 11.5% afeem, 8% tablet lomotil and 4.5% cough syrups. 22% had used alcohol in the past for at least 1 year and 6% had been using benzodiazepines.

Current substance use (during the past 1 month):

13.5% patients had used injectable in the month prior to enrolment in the study. Current use was highest for alcohol at 31.5%. 11% patients had

used an opioid in the past 1 month, 10% had used cannabis and 9% had used benzodiazepines.

Table 2 shows the response to individual items of the attitudes to buprenorphine questionnaire. More than 90% patients agreed that buprenorphine reduces craving for opioids and provides a normal life to a person who has stopped substances of abuse. More than 80% agreed that buprenorphine had done good for people and taking buprenorphine was better than taking substances of abuse. Majority agreed that buprenorphine was one of the best proven ways to stop addiction.

Nearly 40% believed that buprenorphine use was like substituting an addiction with another and gives a high like substances of abuse. Nearly 80% believed that buprenorphine has to be taken for a long time once it is started and nearly 40% said it was difficult to stop as compared to substances of abuse.

More than 80% people felt that buprenorphine should be stopped as soon as possible. 80% patients believed that the worse thing about buprenorphine was that it had to be taken daily. However, only about 20% felt that procuring buprenorphine daily was a bigger problem than procuring substances of abuse.

Side effects: Nearly 70% of patients disagreed or strongly disagreed to the statements that buprenorphine causes slowing of reflexes, reduces sex desire, rots bones, reduces concentration and causes sedation. In fact, 90% patients agreed or strongly agreed to the statement that buprenorphine was a safe drug. Only 20% endorsed that buprenorphine was as dangerous as heroin.

Table 1: Correlation of attitudes towards buprenorphine score with socio-demographic characteristics

Variable	Category (N, %)	Attitudes to BPN score (mean ± sd)	P value
Education	Illiterate (26, 13%)	104.73 ± 24.548	.037*
	< 12 years (136, 68%)	98.66 ± 14.734	
	> 12 years (38, 19%)	105.16 ± 13.544	
Marital Status	Single (78, 39%)	97.04 ± 13.485	.034*
	Married (111, 55.5%)	103.29 ± 17.683	
	Divorced/separated (11, 5.5%)	100.27 ± 16.469	
Locality	Rural (48, 24%)	100.67 ± 21.747	.993
	Urban (152, 76%)	100.69 ± 14.252	
Family type	Nuclear (61, 30.5%)	100.54 ± 14.243	.934
	Joint (139, 69.5%)	100.75 ± 17.179	

Table 2: Attitudes towards individual items of the questionnaire (numbers show percentage)

Sr No		Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Agree
1	Buprenorphine takes away the craving for heroin.	2	.5	1	16.6	79.9
2	Taking buprenorphine is only replacing one addiction with another	12.1	46.2	5.5	26.6	9.5
3	Buprenorphine allows ex-addicts to lead a normal life.	2	5	3	30.2	59.8
4	With buprenorphine you can eventually get off drugs if you want to	4	2.5	1.5	32.2	59.8
5	Buprenorphine in a treatment program gives you a “high” just like heroin.	25.1	27.6	4.5	28.6	14.1
6	Once you’re on buprenorphine you have to keep taking it.	3.5	15.1	2	32.7	46.7
7	People’s reflexes and coordination are not good when they take buprenorphine	43.2	25.1	3.5	15.6	12.6
8	It’s harder to get off buprenorphine than it is to get off heroin.	31.2	28.6	5	22.6	12.6
9	Buprenorphine decreases the sex drive for those who use it.	38.2	21.1	7.5	20.1	12.6
10	Buprenorphine can rot your bones.	46.2	21.1	15.1	10.6	7
11	It’s harder to concentrate when you’re taking buprenorphine	40.2	24.1	5.5	19.1	11.1
12	Buprenorphine has done a lot more good for people than bad.	4.5	3.5	2.5	21.6	67.8
13	The sooner a person stops taking buprenorphine, the better.	5	8.5	3.5	46.2	36.7
14	A reason why buprenorphine has caused problems is because people can get it too easily.	6	59.3	4.5	17.6	12.6
15	Buprenorphine represents an oppression of an African-American minority by a white majority.	60.3	23.6	8.5	3.5	4
16	A person is better off taking buprenorphine than heroin.	5.5	4	1.5	22.6	66.3
17	The worst thing about buprenorphine is having to take it every day.	7.5	12.1	1	29.6	49.7
18	Buprenorphine is more of a problem than heroin ever was	44.7	29.1	5	13.6	7.5
19	Buprenorphine is a safe drug.	2	4.5	2.5	27.1	63.8
20	Buprenorphine is a crutch	4.5	8	3	68.8	15.6
21	Buprenorphine can make you sleepy	44.2	28.6	4.5	14.6	8
22	Buprenorphine has proven to be the best way of quitting heroin.	3	2	2.5	21.1	71.4
23	In the long run, buprenorphine is more helpful than harmful.	9	15.1	4.5	27.1	44.2
24	Heroin addiction is worse than buprenorphine addiction	5	6	2.5	20.1	66.3
25	Buprenorphine programs sometimes act as agents for the police	57.8	14.1	7.5	13.6	7
26	Buprenorphine is as dangerous as heroin.	45.2	26.1	9	12.6	7
27	Buprenorphine has been used more to stop crime than to help addicts.	5	15.6	5.5	39.2	34.7
28	Buprenorphine abuse is happening more and more.	29.1	27.1	9	19.1	15.6

Discussion

This is the first Indian effort to assess the attitudes and experiences of patients towards buprenorphine. The results showed that patients on buprenorphine have highly positive attitudes towards the medication. The findings strongly support that buprenorphine is effective in achieving abstinence from the primary drug of abuse as 87% patients denied using opioids at the time of study. Majority of patients reported that oral buprenorphine was effective in reducing craving and withdrawal. This is a strong indirect evidence for efficacy of buprenorphine in preventing relapse and returning the patients towards normalcy. Earlier studies also showed that buprenorphine is effective in reducing withdrawal and craving, retaining patients into treatment and preventing relapse (Kumar et al., 2009; Petersen et al., 2013; Prakash and Balhara, 2016). Retaining patients in treatment programs leads to better outcomes in terms of relapse prevention and reducing mortality and morbidity associated with illegal drug use (Balhara et al., 2014).

Despite the efficacy of buprenorphine, scaling up of OST has remained a challenge in India. The high cost of running such OST centres and unfavorable attitude of public and policy makers has restricted the scaling up of such centres (Rao et al., 2014). There is growing evidence that patient preferences can lead to better patient outcomes, better retention rates and reduction in dropout rates (Kelly et al., 2012). In previous studies, patients who had taken buprenorphine expressed positive attitudes (Shah et al., 2013) and were satisfied with the drug (Egan et al., 2011; Sohler et al., 2013). The findings from the present study suggest that actual experiences of OST might profoundly affect the attitudes of patients once they are enrolled in the OST programme. Thus, efforts must be made to enroll eligible out of treatment patients into OST so that the benefit of buprenorphine can be passed on to as many persons as possible.

Majority of respondents endorsed that buprenorphine should be stopped as soon as possible in spite of all the positive effects. There can be various reasons for this. *Firstly*, patients on buprenorphine therapy might feel as if they are just substituting one drug for another and are afraid of getting dependent on the drug (this was endorsed by 40% patients in the present study). A previous study also found that fear of getting dependent was the most common harm reported with buprenorphine (Prakash and Balhara, 2016). *Secondly*, there might be concern regarding side effects of buprenorphine if taken for long term. *Thirdly*, a person might consider himself as a drug addict while taking buprenorphine and want to lead a life free of drugs. A study among patients on methadone found that majority were concerned about its side effects and addictive properties and wanted to stop it (Wu et al., 2013). *Fourthly*, daily visits to the center (80% patients in the present study reported this) leading to problems in employment could be the reason for wanting to stop buprenorphine. *Fifthly*, there is stigma attached to the opioid substitution therapy centers since the common view of the public is that buprenorphine is an addictive drug. Though we did not formally assess the reasons for the wish to stop buprenorphine, during the data collection, many patients told the researchers that they would like to lead a life which is free of addiction as well as medication and only then they will consider themselves to be treated. A previous study on attitudes towards methadone also found that patients had highly positive attitudes regarding methadone but wanted to stop it in due course of time (Stancliff et al., 2002). These findings contradict the generally held view by the public that patients who are on buprenorphine are substituting their substances of abuse with a free available addiction and do not want to stop medication (Woo et al., 2017). This has implications for future research and interventions. Well conducted studies are required to carefully weigh the risks and benefits of continuing OST or

tapering it off and exposing the patients to a risk of relapse.

Eighty percent patients reported that the worst thing about buprenorphine was the need to visit the center daily. They had to miss important family events since they could not afford to miss their dose for fear of withdrawal. The dispensing hours of OST center coincide with the working hours of many patients which causes problems with employment also. A previous study also reported problems faced by patients due to daily visits to the centers (Sohler et al., 2013). These findings have importance in terms of future expansion of buprenorphine programs. A long acting preparation of the drug or another drug which is to be taken less frequently might be a boon to such patients. The combination of buprenorphine and naloxone which has less chances of abuse and diversion can be explored as a possible replacement to buprenorphine alone.

Majority of the patients did not agree that buprenorphine causes side effects and 90% felt it was a safe drug. This finding is consistent with the existing literature which suggest that buprenorphine is a safe drug and is not associated with many side effects (Kermode et al., 2011). However, some patients did report concern that they might have side effects if they take it forever.

The findings of the study have some important implications for mental health professionals and policy makers. There is an urgent need to educate out of treatment opioid dependent individuals regarding buprenorphine and other treatment alternatives. Actual experiences with a particular medication may shape retention rates and outcome with therapy. The patients who are already in treatment are a very important source of bringing out of treatment opioid addicts to treatment. Their positive experiences and attitudes can be used to motivate others to enter treatment. Looking at the wide gap between number of patients who might benefit from buprenorphine and those who actually receive it, education regarding myths and misconceptions related to buprenorphine are of paramount importance.

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