

Original Research Article

EFFICACY AND SAFETY OF TAPENTADOL IN OPIOID WITHDRAWAL MANAGEMENT: A LONGITUDINAL QUASI-EXPERIMENTAL STUDY

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ABSTRACT

Background: Withdrawal management is a common challenge with all opioid use disorder treatment modalities. Tapentadol is a novel, centrally acting analgesic with dual mechanism of action, combining mu-opioid receptor agonist with noradrenalin reuptake inhibition in the same molecule with less side effects profile. The aim and objective are to study the effectiveness of Tapentadol in opioid withdrawal symptoms.

Materials and Methods: A Quasi-experimental study among 115 patients with opioid use disorders after assessment on Clinical Opiate Withdrawal Scale (COWS) were given tablet tapentadol and again were reassessed after 1 week and soon the same scale. Data analysed using Epi Info 7.2.4 software. Descriptive data was expressed in terms of frequencies, proportions and ratios. For continuous variables means and standard deviation and 95% confidence intervals (95% CI) were calculated. Scores of the scale before & after intervention was compared using student's t- test and a p value <0.05 was taken as statistically significant.

Results: All the study participants were males, majority unmarried (72.1%) with a mean age of 26.9 years with Standard Deviation of ± 5.04 . Around 57% patients developed any type of side effect. On applying student t test, the average reduction in mean COWS score was 12.87 with 95% CI -13.54 to -12.20 with a p value of <0.0001 which was statistically significant and independent of baseline COWS score of individuals.

Conclusion: Tapentadol is effective in reduction of COWS score in opioid withdrawal patients; hence, opioid withdrawal symptoms with less side effects profile. Tapentadol can be used safely in patients with moderate to moderately severe opioid withdrawal symptoms.

Keywords: Opioid, withdrawal, COWS, tapentadol.

INTRODUCTION

Opioids are primarily used in management of acute and chronic pain.^[1] Opioids are known for their euphoric, tranquilizing, and sedative qualities due to which these are often used recreationally.^[2] Opioid use disorder is characterised by misuse and abuse of opioids and include all sort of disorders related to it.^[3] The persistent use, despite of knowing the adverse consequences are known as opioid use disorders and is a chronic relapsing problem. The disorders are associated with a range of mental and

general medical co-morbid disorders, and with increased mortality. Chronic morbidity as well as mortality due to opioid overdose continues to rise these days.^[4]

Withdrawal from a substance is characterised in the Diagnostic and Statistical Manual for Mental Disorders, 5th edition (DSM-5), as "the substance-specific problematic behavioural change, with physiologic and cognitive components, that is due to the cessation of, or reduction in, heavy and prolonged substance use",^[3] and in the International Classification of Diseases, 10th edition, as "a group

of symptoms of variable clustering and severity occurring on absolute or relative withdrawal of a psycho-active substance after persistent use of that substance”.[5]

Withdrawal management is a common problem encountered with opioid use disorder treatment modalities. When opioid users reduce or abruptly discontinue opioid intake, they experience a broad range of severity of withdrawal symptoms. The common withdrawal symptoms are insomnia, lacrimation, yawning, rhinorrhoea, gastrointestinal symptoms (nausea, vomiting, and diarrhoea) and aching. There are characteristic clinical signs of opioid withdrawal syndrome; which include hypertension, tachycardia, mydriasis and piloerection (i.e. goose bumps). There is relapse to opioid use which often leads to deadly overdose with ineffectively monitoring and management of withdrawal symptoms. A prerequisite for effective opioid withdrawal management is early identification and assessment of withdrawal symptoms.[6-8]

The half-life of the type of opioid used principally determines the time course of opioid withdrawal. For example, there is onset of withdrawal symptoms within twelve hours of last use of heroin which has short half-lives (e.g. 3–5 hours) whereas withdrawal symptoms occurring one to three days after last use of methadone which has longer half-lives (e.g. up to 96 h).[9,10] Similarly, it is also the half-life of the opioid which determines the duration of the opioid withdrawal syndrome. For example, heroin withdrawal lasts four to five days and methadone withdrawal lasts seven to fourteen days but can be even more protracted, in some cases lasting several weeks.[9,10]

There are several treatment modalities for opioid use disorders. Methadone acts like agonists because it fully binds to and stimulates opioid receptors; whereas, Buprenorphine acts like partial agonists and Clonidine and Lofexidine are α_2 agonists.[11,12] Due to non availability of buprenorphine in all settings, other promising alternatives having mu-opioid receptor agonist properties and low to none misuse potential, such as tapentadol / tramadol, can prove beneficial hence should be investigated. However, there is need of randomized controlled trials to definitively establish the suitability of medications that can prove beneficial for managing withdrawal symptoms in such patients.

Tapentadol is known to act as an analgesic with centrally acting properties, having dual mechanism of action. Tapentadol acts as mu-opioid receptor agonist in addition to nor adrenaline reuptake inhibitor. It has an improved side effect profile on comparing to opioids and other analgesics including nonsteroidal anti-inflammatory drugs (NSAID's). Tapentadol is a useful analgesic to treat neuropathic pain or other acute or chronic pain due to its dual mechanism of action.[13]

Due to its dual mechanism of action and less side effects profile, tapentadol can be used safely to

manage the symptoms of opioid withdrawal in patients with opioid use disorders. There is scarcity of data on use of tapentadol in opioid use disorders and about side effects of its use especially in our settings. So, this study was planned to fill this gap in knowledge of this use.

Aims and Objectives

1. To study the effectiveness of Tapentadol in opioid withdrawal symptoms.
2. To study the side effects of Tapentadol use in opioid withdrawal.

MATERIALS AND METHODS

Study Design and Setting: The current study was a Quasi-experimental study among patients of opioid use visiting Psychiatry OPD of Dr RKGMC Hamirpur; from November 2022 to April 2023. A total of 145 patients with opioid use disorders (as per ICD 10 criteria) visiting Psychiatry OPD were assessed on Clinical Opiate Withdrawal Scale (COWS),[17] and based upon the severity of their withdrawal symptoms on the scale; they were started on tablet tapentadol according to severity. On the basis of same scale (COWS) patients were classified as mild (score 5-12), moderate (score 13-24), moderately severe (score 25-36) and severe (score more than 36) opioid withdrawal. Patients with mild withdrawal score were not given tablet tapentadol. Patients with moderate withdrawal score were given tablet tapentadol 300 mg per day in three divided doses. Patients with moderately severe withdrawal score were given tablet tapentadol 400 mg per day in three to four divided doses. Patients in which tablet tapentadol was contraindicated and patients with severe cognitive defects or acute severe psychosis and those who were not well oriented to time, place & person were excluded from the study. Among fifteen patients tablet Tapentadol were contraindicated hence excluded from the study. So, after all adjustments out of 145 patients only 115 were included in present study. All the participants were assessed on the basis of Clinical Opiate Withdrawal Scale (A standardised questionnaire), put on treatment and again were reassessed after 1 week and soon the same scale. The UKU side effect rating scale,[17] was used to study the side effects of Tapentadol use in opioid withdrawal.

Tools: Clinical Opiate Withdrawal Scale (COWS) - Assessment of study participant was done using a standardized Clinical Opiate Withdrawal Scale (COWS). Due to its time-efficiency (i.e., can be completed within 2 min) Clinical Opiate Withdrawal Scale (COWS) is a widely used 11-item clinician-administered instrument. It is one of the most widely used scales and assesses almost all the signs and symptoms related to opioid withdrawal which include anxiety or irritability, gastrointestinal upset, restlessness, bone or joint aches, sweating, rhinorrhea, tremor, gooseflesh, yawning, pupil size, and pulse rate. It consists of scores from 0 to 47

where scores from 5 to 12 are considered mild, scores from 13 to 24 are considered moderate, scores from 25 to 36 are considered moderately severe and scores more than 36 are considered severe withdrawal. (7, 14, 15)

Severity of Opiate Dependence Questionnaire (SODQ) - It consists of 20 items and is a 4-point scale (0 never–3 always). It has a maximum score of 60 and the scores correlate with subjective feelings of dependence. Its correlation with severity of opiate use and with subjective feelings of dependence is >0.95 .^[16]

Statistical Analysis: After obtaining the data from participants it was entered in Microsoft excel sheet. After data cleaning it was analysed using Epi Info 7.2.4 software. Descriptive data was expressed in terms of frequencies, proportions and ratios. For continuous variables means and standard deviation and 95% confidence intervals (95% CI) were calculated. Scores of the scale before & after intervention was compared using student's t- test and a p value <0.05 was taken as statistically significant.

Ethical approval: A prior approval of Institutional Ethics Committee was taken before start of the study. Ethical consideration in concordance with the Helinski Declaration was adhered to. A written informed consent explaining the nature and intend with pros and cons of the study was obtained from

all the participants prior to their enrolment to the study. Proper care was taken to maintain confidentiality and integrity of study participants.

RESULTS

The present study was conducted to assess the severity of opioid withdrawal symptoms and efficacy and safety of Tapentadol in management of patients with opioid withdrawal symptoms attending psychiatric outdoor patient Department of Dr RKGMC Hamirpur from November 2022 to April 2023. A total of 145 participants with opioid use disorders (as per ICD 10 criteria) visiting psychiatry OPD of a tertiary care institute were considered for the study initially but 15 patients didn't give consent and 15 were excluded from the study after applying inclusion and exclusion criteria. Finally, 115 participants were enrolled for the study.

Sociodemographic variables: All the study participants were males, majority unmarried (72.1%) and with a mean age of 26.9 years having a Standard Deviation of ± 5.04 (Table 3, Figure 3). More than 3/4th of the patients (78.3%) were found to be in the age group of 21 to 30 years, whereas 16.5 % between 31-40 years and only 4.4 % < 20 years and only 0.87% above 40 years.

Table 1: Sociodemographic distribution of Participants (n=115)

Variable	Category of variable	N (115)	%
Age (in years)	<20	5	4.4
	21-30	90	78.3
	31-40	19	16.5
	>40	1	0.8
Mean age		26.97 $\pm$ 5.04 Years	
Education	Professional	17	14.8
	Graduation or above	39	33.9
	Senior Secondary or Equivalent	37	32.2
	Matriculation or below	22	19.1
Occupation	Govt. Job/ professional	7	6.1
	Private Job/ shopkeeper	44	38.3
	Worker/Drivers	28	24.3
	Student	10	8.7
	Unemployed	26	22.6
Type of family	Nuclear	48	41.7
	Joint	67	58.3
SES Class(BG Prasad 2022)	Upper Class	18	15.6
	Upper Middle	46	40.0
	Lower Middle	45	39.1
	Lower Class	6	5.2

Surprisingly around half (49%) of the study participants were having education of graduation or above or professional with around 22% from technical education stream and 1.5% from pharma graduates.

Occupationally around 62% of these participants were either unemployed or engaged in some private work or own business whereas 9% still students and

6% were professional or govt servants. Majority (80%) of the participants belonged to middle class of SES.

About one fourth (27%) of the study participants accepted of using opioids through intravenous route while 4% were having Hepatitis C co-infection due to that but none of the participants were having HIV positivity.

Table 2: Important Baseline attributes of study participants

Variable	Category of variable	N (115)	%
Current Intra venous drug use (IDU)	Yes	31	26.9%
	No	84	73.1%
Hepatitis C Positivity (HCV)	Yes	5	4.4%
	No	110	95.6%
HIV Positivity	Positive	0	0
	Negative	115	100%

Majority (73.1%) of the study participants were using opioids by oral route whereas about 1/4th (26.9%) of them were using them intravenously.

None of the study participants were having HIV reactivity while 5 participants were having hepatitis C positivity.

Table 3: Baseline assessment scores of study participants

Variable	Category of variable	N (115)	%
Baseline SODQ score	Mild (<21)	0	
	Moderate (22-42)	0	
	Moderately Severe (43-63)	35	30.2
	Severe (> 63)	80	69.8
Mean SODQ score		67.19 ± 6.25	
Baseline COWS Score	Mild	0	0
	Moderate	78	67.8
	Moderately Severe	37	32.2
	Severe	0	0
Mean Baseline COWS score		22.05 ± 3.35	

Baseline SODQ scores of study participants ranged from 55-80 with mean SODQ score of 67.19± 6.25. All were either in moderately severe or severe SODQ score range while none were having mild or moderate severity of symptoms as per baseline SODQ score.

Range of baseline COWS score was 17-30; with median score of 21 and mean baseline COWS score of 22.05± 3.35. All of the study participants were either moderate (67.8%) or moderately severe (32.2%) COWS score category. As Tapentadol is

only given to moderately severe or severe COWS score participants only so 78 were given Tapentadol 300 mg per day and rest 400 mg per day for a period of 1 week. After 1 week of treatment with tapentadol all the participants were again re-assessed on COWS tool for effectiveness of drug and also for presence of side effects (if any) and severity of these side effects occurred due to tapentadol use for 1 week. Effectiveness of drug was tested by comparing the initial baseline COWS score with that after Tapentadol therapy.

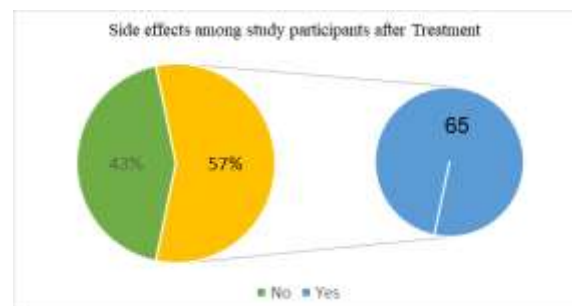
Table 4: Comparison of different scores among study participants

Sr. No.	Particulars	Mean	Std Dev
	Baseline COWS Score	22.05	3.35
	Post treatment COWS Score	9.18	1.40
	Reduction in COWS score after Treatment	12.87	0.34
95% Confidence Interval			-13.54 to -12.20
P value			P < 0.001

Post treatment COWS score ranged from 7-12 with a median score of 9 and mean score of 9.18± 1.40. On applying student's t test, pre and post treatment for reduction in COWS score; the average reduction in COWS score was 12.87 (95% CI: -13.54 to -12.20) with a p value of <0.001 which was statistically significant and also this reduction was independent of baseline COWS score of individuals. Meaning thereby that tapentadol is effective in reduction of COWS score in opioid withdrawal patients.

Study participants were also evaluated for development of side effect after drug use. Total 65 (57%) participants developed any type of side effect after taking Tapentadol and mostly gastrointestinal with a few extrapyramidal side effects in the form of headache and dizziness. Among the gastrointestinal Nausea was the most common (45%) one followed by constipation (33%) but none of these side effects

were so severe that needed stoppage of the drug in between and these side effects didn't have any correlation with the increasing dose of Tapentadol or severity of COWS score.

**Figure 1: Tapentadol Use side effects distribution among study participants**

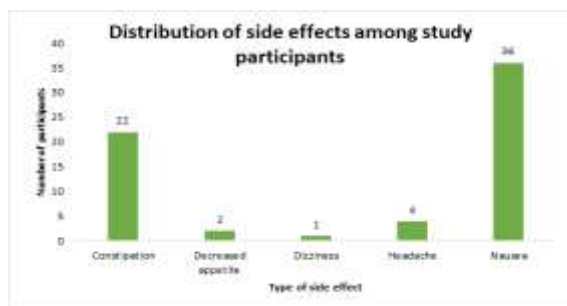


Figure 2: Side effects of Tapentadol therapy among study participants

DISCUSSION

The persistent use of opioid despite of knowing the adverse consequences are known as opioid use disorders and is a chronic relapsing problem. Withdrawal management is a common problem encountered with opioid use disorder treatment modalities. When opioid users reduce or abruptly discontinue opioid intake, they experience a broad range of severity of withdrawal symptoms. There is relapse to opioid use which often leads to deadly overdose with ineffectively monitoring and management of withdrawal symptoms. A prerequisite for effective opioid withdrawal management is early identification and assessment of withdrawal symptoms.^[6-8]

The present study which was designed to study the effectiveness and safety profile of tapentadol for management of patients with opioid withdrawal symptoms was Quasi-experimental study among patients with opioid use visiting Psychiatry OPD of Dr RKGMC Hamirpur; from November 2022 to April 2023. Total 115 eligible patients who fulfilled inclusion and exclusion criteria and obtained written informed consent are enrolled in the study. Out of 115 participants enrolled for the study; majority were unmarried males (72.1%) with a mean age of 26.9 ± 5.04 years. More than 3/4th of the patients (78.3%) were found to be in the age group of 21 to 30 years. These findings in this study is comparable to findings in the studies conducted by Jhanjee S, Sethi S (2016),^[18] and Sidana A et al. (2019),^[19] in which majority of the patients were males as 97.1% and 99.1% respectively. Less number of female patients could be due to less involvement with opioid use disorders or stigma associated with opioid use and also reluctance to seek treatment in females even if they are using opioids. Further, finding is comparable to other studies done by Rather YH et al. (2013),^[20] in which the mean (SD) age of patients was 26.8 years (SD 7.37). Farhat S et al. (2015),^[21] observed mean age of the patients was 27.6 years and were of young age group (20–30 years). Bhat BA et al. (2019),^[22] also observed the mean age of patients was 27.55 years (± 7.26) with majority of patients (83.78%) between 20 and 40 years of age. In other studies, according to Dunn KE, Tompkins DA, Bigelow GE, Strain EC (2017),^[23] and Kelly Dunn, Cecilia Bergeria,

Andrew S. Huhn, Eric C. Strain (2020),^[24] 85.4% were men with mean (SD) age 28.9 (10.4) years and 41.2 (SD: 10.2) years respectively. Mattoo SK, Basu D (2003) found that men had an age range of 17-50 years (mean: 30.17 ± 7.00).^[25] Approximately half (49%) were graduate and above and half below. Similarly, study conducted by Kumar S et al. (1996),^[26] revealed that 52% had completed 10 years of schooling. Sidana A et al.,^[19] (2019) found that 45.8% patients were educated up to 10th/12th class. However; Jhanjee S, Sethi S,^[18] (2016) found around 33% were illiterate because their study population included an urban resettlement colony plus jhuggi cluster and good literacy rate in our state (Census 2011) could be the possible reason for this difference. Occupationally, majority of participants in our study were either Private Job/ shopkeeper (38%) followed by worker/ drivers (24%) and unemployed (23%). Students account for 9% of the participants and Govt. Job/ professional were 6%. The study conducted by De B et al.,^[27] (2003) Srivastava M,^[28] (2015) and Sidana A (2019),^[19] also found that 56%, 67% and 48.7% patients were working respectively. Being working and earning money as well as more social interactions might be the reason behind in this occupation. According to Mattoo SK, Basu D (2003),^[25] the employment profile was: 56% employed 26% unemployed and 17% students and 40% of the patients were not earning. The majority of participants were unmarried (64.1 %) and unemployed (93.2 %) as per study conducted by Kelly Dunn, Cecilia Bergeria, Andrew S. Huhn and Eric C. Strain (2020).^[24] The marital profile was: 50% never married, 47% married and 3% divorced Mattoo SK, Basu D (2003).^[25] Majority (80%) of the participants belonged to Middle class of SES as was found in our study. In study conducted by Rather YH et al. (2013),^[20] and Srivastava M (2015),^[28] 56% and 82% patients belonged to the Lower MSES and MSES respectively. The possible reason in study over heroin dependent patients may be that patients from higher socio-economic class of population go to private practitioners for de addiction.

About one fourth (27%) of the study participants accepted of using opioids through intravenous route while 4% were having Hepatitis C co-infection due to that but none of the participants were having HIV positivity. This finding is comparable to the finding study conducted by Zafar T (2001),^[29] in which majority reported current non-injection drug use and Jhanjee S, Sethi S (2016),^[18] in which 67.3% had a history of injecting drug. The study conducted by Mahajan P et al. (2016),^[30] observed that prevalence of HCV in their study came to be 38.12%. Also study conducted by Bangun D et al.,^[31] (2006) observed that patients had high frequency of positive Hepatitis C test. The prevalence of HCV/HIV co-infection among injection drug users was 11% (95% CI 5–16%) as per Malekinejad M et al. (2015).^[32] High prevalence of positive Hepatitis C patients could be due to low educational

background in both the studies. In our study most of the patients had qualification more than 10th -12th standard and had knowledge about risks of sharing syringes or equipment.

Baseline SODQ scores of study participants ranged from 55-80 with mean SODQ score of 67.19 ± 6.25 indicating substantial variation in their degree of opioid dependence. Baseline SODQ scores of study participants all either in moderately severe (30.2%) or severe (69.8%) SODQ score and none having mild or moderate severity of symptoms as per baseline SODQ score. In comparison to other studies, the mean SODQ score obtained was 60.5 (SD 8.3) and most of the participants had an SODQ score of >30 , indicating severe opioid dependence Mattoo S K et al. (2020).^[33] Also, according to Duncan R et al. (1994) [34] mean SODQ score of 59 ± 14 and Soni R et al. (2017),^[34] mean score obtained were 46.8 ± 10.1 , indicating significant dependence. Whereas the baseline COWS score in our study revealed that all of the study participants were either moderate (67.8%) or moderately severe (32.2%) score category (the baseline COWS score 17-30 with median score of 21) and mean baseline COWS score was 22.05 ± 3.35 . Accordingly, as per COWS baseline severity 78 participants were given tablet Tapentadol 300 mg per day in divided doses and the rest of participants were given tablet Tapentadol 400 mg per day in divided doses for a period of 1 week. Around 65 (57%) patients developed any type of side effect after taking tablet Tapentadol and mostly gastrointestinal with a few extrapyramidal side effects in the form of headache and dizziness. Among the gastrointestinal, nausea was the most common (45%) one followed by constipation (33%) but none of these side effects were so severe that needed stoppage of the drug in between and these side effects didn't have any correlation with the increasing dose of Tapentadol or severity of COWS score. In comparison to other studies, the most common treatment-emergent adverse events during treatment with tapentadol included nausea, diarrhea, anxiety and dizziness Schwartz S et al. (2011).^[36] Also, nausea, vomiting, constipation, dizziness, somnolence, and headache as per Desai B et al. (2014).^[37] Further, headache (13.1%), nausea (11.8%), and constipation (11.1%) were the mostly encountered treatment-emergent adverse events (incidence $\geq 10\%$; $n = 1154$) observed by Buyank R et al. (2015).^[38]

Effectiveness of drug in our study was tested by comparing the initial baseline COWS score with that after Tapentadol therapy. On applying student t test, the average reduction in mean COWS score was statistically significant with a p value of <0.0001 which and this reduction was independent of baseline COWS score of individuals. Meaning thereby that tapentadol is effective in reduction of COWS score in opioid withdrawal patients. According to other studies; patients with Opioid Withdrawal Symptoms were improved a mean of 7.6 units on the COWS at 30 min after 10 mg IM

methadone administration ($P < 0.001$) which was a statistically significant improvement. Additionally, since the COWS score can discriminate the clinical severity of opioid withdrawal, a reduction in 7.6 units is likely to reduce the severity in most patients to lower degree. In fact, 47 of the 57 patients in the primary analysis fell by at least one severity grade on the COWS scale.^[39] Also, Lauren RK et al. (2019) enrolled 63 patients where baseline COWS score was similar (median score 11).^[40] Further, the mean score on day 1 was 10.5 (SD 4.5, range 2–27); among patients with a recorded clinical opioid withdrawal (COWS) score, as per study conducted by Taylor JL et al. (2022).^[41]

CONCLUSION

The present study concluded that all participants were males, majority unmarried (72.1%) with a mean age of 26.9 ± 5.04 years; majority in age group of 21 to 30 years and almost half (49%) graduate and above. About one fifth (22%) of them were from technical education stream, 3/5th (62%) of these participants were either unemployed or engaged in some private work, majority (80%) belonging to Middle class of SES. About one fourth (27%) of the study participants accepted of using opioids through intravenous route while only 4% were having Hepatitis C co-infection none with HIV. Baseline SODQ scores of study participants ranged from 55-80 with mean SODQ score of 67.19 ± 6.25 . So, all either in moderately severe or severe SODQ score as per baseline SODQ score. The baseline COWS score ranged 17-30 with median score of 21 and mean score of 22.05 ± 3.35 . All of the study participants were either moderate (67.8%) or moderately severe (32.2%) score category. Around 57% patients developed any type of side effect after taking Tab Tapentadol and mostly gastrointestinal with a few extrapyramidal side effects in the form of headache and dizziness. Among the gastrointestinal side effects nausea was the most common (45%) side effects followed by constipation (33%). Post treatment COWS score ranged from 7-12 with a median score of 9 and mean score of 9.18 ± 1.40 . Average reduction in mean COWS score was 12.87 (95% CI -13.54 to -12.20) with a p value of <0.0001 which was statistically significant and this reduction was independent of baseline COWS score of individuals. Tapentadol is effective in reduction of COWS score in opioid withdrawal patients with minimal side effects in the form of gastro intestinal disturbances and that also of not much severity.

Recommendations: On the basis of results and conclusion of present study it can be recommended that opioid withdrawal management is a big challenge in Opioid use disorder patients even in tertiary care hospitals in Himachal Pradesh. On the basis of this study it is observed that unmarried

unemployed males have more engaged in opioid use disorders. Education does not prove to be protective from opioid use and more so in technical stream. 4-5% opioid use participants are co-infected with Hepatitis C.

Tapentadol was quite effective in opioid withdrawal symptoms with minimal side effects as seen by reduction in COWS score. Tapentadol itself is a good alternate for management of opioid withdrawal symptoms but for better comparison of effectiveness and safety profile; more studies that also randomised controlled trials (RCT) in comparison to conventional treatment are needed. Involvement of more deaddiction centres for evaluation of effect of demographic are needed.

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