



AN OBSERVATIONAL STUDY TO ASSESS THE RETENTION RATE OF OPIOIDS WITHDRAWAL THERAPY AMONG OPIOIDS ADDICTED PERSONS IN WESTERN RAJASTHAN

Public Health

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ABSTRACT

Aim:- The aim of this study was to study retention rate of opioid withdrawal therapy among opioid addicted persons. **Methodology:-** This was hospital based observational study include individuals who diagnosed as opioid dependence and initiated Various Drug Therapy were follow up for 3 months of period. Multiple assessments were done to find out retention rate of withdrawal therapy, severity of opioid dependence & withdrawal and quality of life at baseline, 1 and 3 months. The secondary outcome was assessing the change observed in the above listed variables. This study was conducted in Department of Pharmacology and Psychiatry, Dr. S. N. Medical College, Jodhpur, Rajasthan. **Results:-** A total 100 number of patients were included in this study. In our institution, tramadol based opioid withdrawal therapy was available. The result of this study was 68 percent retention rate at one month follow-up and 51 percent at three months follow-up. Quality of life was improved in retained cases after 3 months of follow up **Conclusion:-** The available opioid withdrawal therapy was tramadol based and this therapy offers a viable alternative to the existing options for the management of opioid use disorders It offers certain major advantages such as easy and wide availability and low abuse liability but it is effective mainly in mild to moderate opioids addiction.

KEYWORDS

Opioid substitution therapy, Quality of life, tramadol retention rate.

INTRODUCTION-

India is situated between the two largest illicit opium producing regions of the world – “Golden Crescent” and “Golden Triangle,” which makes it vulnerable for being both a destination and transit route for opioids¹. According to a survey of Ministry of Social Justice and Empowerment (MoSJE), alcohol is the most common psychoactive substance used by Indians. After Alcohol, Cannabis and Opioids are the next commonly used substances in India About 2.1% of the country's population (2.26 crore individuals) uses opioids which include opium heroin and a variety of pharmaceutical opioids. Nationally, the most common opioid used is heroin (1.14%) followed by pharmaceutical opioids (0.96%) and opium (0.52%). According to a study “Opium Addiction among Rural Population in Desert Districts of Western Rajasthan” there were 1200 opium or doda addicts in the rural population of 3640. The overall addiction rate was 8.4 % in Barmer, 7.9% in Jaisalmer and 6.9% in Bikaner districts of Rajasthan. The addicts were all males and a negligible number of females (0.3%) in the surveyed villages². In rural areas of western Rajasthan opium is consumed in social gatherings, marriages and even at condolence.

According to DSM-5 Criteria for Diagnosis of Opioid Use Disorder opioid addiction is define as “There is a persistent desire or unsuccessful efforts to cut down or control opioid use and opioids are often taken in larger amounts or over a longer period of time than intended”.

There were many studies about prevalence of opioid addiction, but we did not find any study about retention rate of opioid therapy in western Rajasthan. Hence, we decided to study about retention rate of opioid withdrawal therapy among opioid addicted persons in western Rajasthan population.

AIM AND OBJECTIVES

This study was aimed to identify retention and dropout rate of opioid withdrawal therapy on opioid addicted persons in western Rajasthan population.

Primary Objective:

Determine retention and dropout rate of opioid withdrawal therapy in western Rajasthan.

MATERIALS AND METHODS

A total of 100 participants with opioid dependence were recruited by convenience sampling. The primary outcome was treatment retention at 1 month and 3 months post entry into maintenance treatment. Multiple assessments were done for the severity of opioid dependence and withdrawal and quality of life baseline and 1 and 3 months.

Study Design

A hospital based prospective observational study.

Study Setting

This study was conducted in department of Pharmacology, Dr SN medical college and department of Psychiatry, MDM hospital Jodhpur, a tertiary care addiction treatment center in western Rajasthan. At this center, the largest section of patients came from the western part of Rajasthan state. This center provides opioid withdrawal management as well as maintenance treatment services on an inpatient and outpatient basis. For maintenance treatment, tramadol-based treatment was available. The decision of maintenance treatment was taken through shared decision making between the treating psychiatrist, patient, and family members. Therefore, the investigator was not influenced the treatment decision in any way.

Population

OPD/IPD based patients of opioid withdrawal therapy in department of psychiatric MDM hospital, Jodhpur.

Study Time

Duration of Study was over a period of six months.

Sample Size

$$n = \frac{(Z_{1-\alpha/2})^2 P(1-P)_E}{(1.96)^2 \times 57 \times 43 / (11.4)^2} = 72$$

Where,

$Z_{\alpha/2}$ = Standard normal deviate for 95% confidence interval (taken as 1.96)

P = Median retention rate across observational studies, was approximately 57% (taken as 57 as reported by Aisling Ma'uire O'Connor et al)

E = Absolute allowable error (taken as 20%) Sample size calculated to be minimum 72 subjects, which was rounded off to 100 patients.

Inclusion Criteria:

All of them were included after written informed consent. Clearance was taken from the institutional ethics committee before recruiting the cases. Patients diagnosed with opioid dependence syndrome as per DSM 5 criteria, aged 18–70 years, and were taking opioid withdrawal treatment.

Exclusion Criteria:

Participants were excluded from the study if they were unwilling or unable to give consent, having dual diagnosis (opioid dependence with severe mental illness, viz., schizophrenia, bipolar disorder, and

depressive disorders assessed and excluded by Mini International Neuropsychiatric Interview [MINI] and clinically significant illness (e.g., hepatitis, tuberculosis, acquired immune deficiency syndrome). Lactating mother and children were excluded.

METHODOLOGY:

Patients attending the outpatient were approached and explained about the study. Those who will give the informed consent was assessed on MINI to rule out any severe mental illness. Those fulfilling the diagnosis was further assessed on inclusion and exclusion criteria. All the included subjects in the study were assessed at baseline during starting of therapy. The participants were observed prospectively and the reassessments was done at 1 months (±2 weeks) and 3 months (±2 weeks) follow up period.

Statistical Analysis

The data collected during the study was compiled using a Microsoft Excel spread sheet and analyzed statistically using the statistical package for the MedCalc statistical Software version 20.115 for window editions. Qualitative data were presented as number, percentage and Quantitative data were presented as mean±SD. Comparison between groups was done by fisher exact test, χ^2 -test, un paired & Mann Whitney u test. P value less than 0.05 was considered to be statistically significant.

OBSERVATIONS AND RESULTS-

Total 100 opioids addicted persons, who fulfilled inclusion criteria were included in this study was conducted in department of pharmacology in association with department of psychiatry at MDM hospital, attached with Dr. S. N. Medical College, a tertiary care teaching hospital, Jodhpur, Rajasthan.

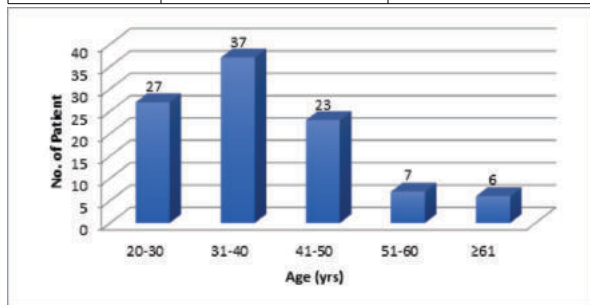
Demographic Profile:

Age wise distribution of study patients

Out of 100 patients, maximum patients were of age group 20-30 yrs. (27%), 31-40yrs (37%), 41-50yrs (23%) and 51-60yrs (7%) & above 61yrs (6%) were minimum in number. Mean age was 38.17 ± 10.83 years.

Table 1: Distribution of opioids addicts according to age.

Age (yrs)	No. of patients	Percentage
20-30	27	27.00
31-40	37	37.00
41-50	23	23.00
51-60	7	7.00
≥61	6	6.00
Total	100	100.00



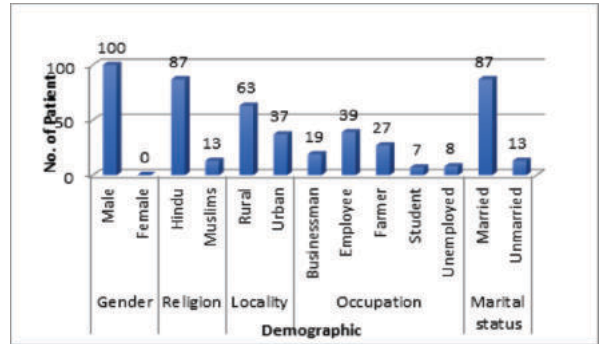
Distribution of opioids addicts according to gender, religion, locality, occupation and marital status.

All patients were male 100%. Out of 100, Hindu was 87% and 13% from Muslim community. 63% from rural and 37% from urban background. On the basis of occupation 39% employee, 8% unemployed, 19% businessman, 27% farmer and 7% were students. Married persons were 87% and 13% unmarried.

Table 2: Distribution of opioids addicts according to gender, religion, locality, occupation and marital status.

Demographic	No. of patients	Percentage
Gender	Male	100
	Female	0
Religion	Hindu	87
	Muslims	13

Locality	Rural	63	63.00
	Urban	37	37.00
Occupation	Businessman	19	19.00
	Employee	39	39.00
	Farmer	27	27.00
	Student	7	7.00
	Unemployed	8	8.00
Marital status	Married	87	87.00
	Unmarried	13	13.00

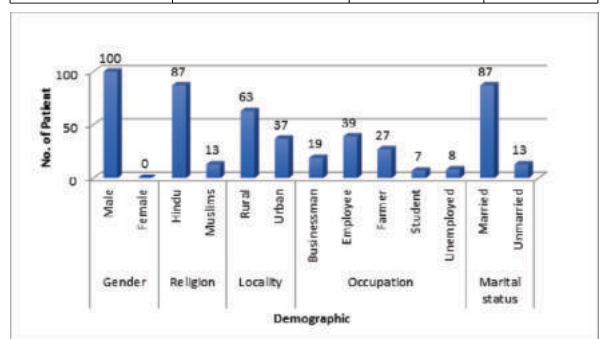


Distribution of opioids addicts according to education status and duration of opioid consumption.

Most users were literates. Only 10% were illiterate. 68 percent had completed five to 12 years of schooling. 22% users were graduate or above. Duration of opioids consumption in half of users (50%) was 1 month to 5 years followed by 28% (6-10 yrs.) and 22% (more than 10 yrs.).

Table 3: Distribution of opioids addicts according to education status and duration of opioid consumption.

Demographic-2	No. of patients	Percentage
Education status	Uneducated	10
	Primary	16
	Middle	23
	Secondary	15
	Higher secondary	14
	Graduate & above	22
Duration of opioid consumption	<1 year	7
	1-5	43
	6-10	28
	>10	22

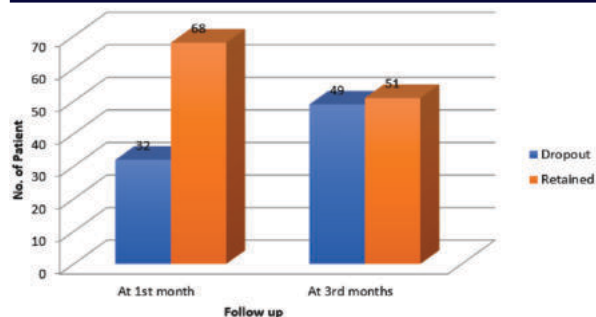


Retained and dropout percentage of opioids addicts at first and third month.

The retention rate of users is given in the graph. The retention rate was 68 percent at the first-month follow-up and 51 percent at three months follow-up while dropout rate was 32% at first month follow-up and 49% at three months follow up.

Table 4: Retained and dropout percentage at first and third month.

Follow up	Dropout		Retained	
	N	%	N	%
At 1st month	32	32.00	68	68.00
At 3rd months	49	49.00	51	51.00



DISCUSSION

Abuse of narcotics and narcotic analgesics for relief of pain may be a global phenomenon but initiation into opium consumption as part of social custom is exclusive to rural areas of western Rajasthan giving it the unenviable distinction of being home to the large number of opium addicts. The total number of registered addicts all over India was 80,809 in 1975, (Reports of Expert Committee Drug Abuse in India, 1976)³. According to Purohit et al (1988), 12.67% of adult males in villages of Rajasthan are opium dependent. In another study, 11.81% of adult males were opium dependent in village Joliyali in Jodhpur district⁴. The Western Rajasthan region is known for its traditional use of raw opium in the form of Afeem and Doda. The ethnographic information suggests that opium use is in many ways integrated into the sociocultural fabric of the local community⁵. Mathur et al carried out a study in 19 villages in Jodhpur district and concluded that 7.1% of adult males in villages of Rajasthan are opium dependent⁶.

All the participants in the present study were men. Previous two studies reported that 99.5% treatment-seeking patients were men^{7,8}. Therefore, “all-male participants” in our study was reflective of the general treatment-seeking pattern in the region. The study results were based on a single center, which likely caters to severe opioid use disorders. Therefore, these results should not be generalized to other population contexts.

In this study the mean age of opioid users was 38.17 years which is comparable to study conducted by Maithili Kadam et al, 2017, the mean age of that study was 37.8 ± 12.16 years⁹. The earlier age at development of a dependence was significantly earlier in the opioid dependence and is potentially attributable to the highly addictive properties of opioid.

In a systemic review study, 67 studies were included in the review (4 RCTs and 63 observational cohort studies; N = 294,592), all assessing factors associated with retention in OST or treatment dropout. The median retention rate across observational studies was approximately 57% at 12 months, which fell to 38.4% at three years¹⁰. In this study the retention rate is 68 percent at first month and 51 percent at third month.

CONCLUSION

There was a significant correlation between all the four domains of physical health, psychological health, social relationships and environment QOL, with all four domain-wise scores showing significantly strong positive correlation with the baseline QOL score. In Our study the retention rate is 68 percent at first month and 51 percent at third month. A study with large sample and multiple centers is needed to investigate changes in Quality of Life (QoL) following opioids dependence treatment. Other drugs for opioids dependence treatment could be used for patients for finding changes in Quality of Life (QoL).

Limitation Of The Study

This treatment was completely OPD basis and most of users were from rural background and other districts (Barmer, Jaisalmer, Jalore and Nagaur) so retention rate was slightly low. Because dose adjustment was needed for moderate to severe addicts and in absence of this, most of users dropped out due to withdrawal symptoms and repeated follow-ups were also not possible for long distance users.

The study included small sample size and short duration of follow-up of four and half month, longer duration of follow-up and big sample size could have predicted the impact of certain treatment related variables on QoL. The other limitation of this Study was that this study was conducted in a single Centre only.

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Conflict of Interest:

No conflict of Interest.

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