Original Research Paper

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A COMPARATIVE STUDY OF SOCIO-DEMOGRAPHIC PROFILE, QUALITY OF LIFE AND BURDEN ON CAREGIVER IN PATIENTS ON BUPRENORPHINE MAINTAINANCE THERAPY AND METHADONE MAINTENANCE THERAPY FOR OPIOID DEPENDENCE.

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ABSTRACT **Background:** Substance use disorder is a major public health problem worldwide. In India National Household Survey1 of Drug Use in the country was the first systematic effort to document the nation-wide prevalence of drug use and the survey reported that alcohol (21.4%) was the primary substance (apart from tobacco) followed by cannabis (3.0%) and opioid (0.7%). The Drug Abuse Monitoring System reported that2 inpatient treatment centres found the major substances were alcohol (43.9%), opioids (26%) and cannabis (11.6%).

Objectives: The aim of this study is to assess the socio-demographic profile of opioid dependent patients, burden on their caregiver and compare qualities of life who were on Buprenorphine and Methadone substitution therapy. Methods: A cross-sectional study was conducted in the Drug De-addiction Clinic and Opioid Substitution Therapy Centre, in Department of Psychiatry, Government Medical College, Kota, India. Study includes 80 opioid dependent patients who were on Buprenorphine and Methadone substitution therapy, socio-demographic data, quality of life of patients and burden on their care givers were analysed by using SPSS version 21 software.

Results: In the present study all patients were male, ages were between 20 to 62 years, 71.25% were married, 68.8% were Hindus and 33.3 % Muslims. Majority (85%) of patients were from urban background and majorities (91.25%) of were educated up to 10th standard. The patients who were on Buprenorphine maintenance therapy had comparatively better quality of life than the patients who were on methadone maintenance therapy. Burden on caregivers were less and statistically significant in all five domains in Buprenorphine maintenance therapy patients as compared to the patients who were on methadone maintenance therapy.

KEYWORDS : Opioid dependence, quality of life, caregiver burden.

INTRODUCTION:

The word Opioid describes a class of psychoactive compounds, both naturally occurring and chemically synthesized, that are related to opiates: alkaloid compounds found as natural products in the opium poppy plant, *Papaver somniferumi.* Opioids are obtained from the juice of an unripe poppy capsule of plant; the milky juice is derived and crushed to make powdered opium which contains a number of alkaloids. Opioids can be taken orally, snorted intra-nasally, and injected intravenously or subcutaneously.

The National Institute of Health and Clinical Excellence (NICE) in the UK recommend both Buprenorphine and methadone as first line treatment for medically assisted withdrawals from opioids.

The Dependence syndrome[3] has been defined in the 'International Statistical Classification of Diseases and Related Health Problems' (10th revision; ICD-10) as a "cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and that typically include a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences.

MATERIAL & METHOD:

Study Design: Cross-sectional study.

Study Participants: The study participants consisted of consenting 80 patients of opioid dependence in which 40 patients were registered for Methadone Maintenance Therapy **(MMT)** and 40 were registered for Buprenorphine Maintenance Therapy **(BMT)**.

Tools Of Study:

A Semi structured specially designed proforma that includes

1. Socio-demographic details and clinical profile of patients & caregivers.
2. Clinical profile sheet using Quality Of Life Assessment scale, WHOQOL– BREF (Hindi-version).
3. Burden Assessment Schedule.

The Inclusion criteria (for patients)- Patients fulfilling diagnostic criteria of Opioid dependence as per ICD-10 guideline, had history of dependence for at least 6 month, taking either Methadone or Buprenorphine maintenance therapy for at least for one month and is able to understand the questionnaire and ready to give informed consent were included in this study.

The exclusion criteria (for patients)- Patients having significant physical, surgical or psychiatric illness, or having co-dependence with other psychoactive substances were excluded from the study.

The Inclusion criteria (for caregiver)- Caregiver living with the patient for at least 6 month, directly involved in the care of the patient and older than 18 years were included in this study.

The exclusion criteria (for caregiver)- Caregivers who had significant physical, surgical or psychiatric illness and having any history of substance dependence were excluded from the study.

RESULTS AND DISCUSSIONS:

In the present study all patients were male, the age varies between 20 to 62 years and the mean age was found to be 38±10.6 years with majority (37.5%) of patients being in the age group 31-40. The mean age of the patients who were on **(MMT) and (BMT)** was 40.4 yrs and 35.6 years respectively **(Table 1)**.

A study conducted by Biswajit de et al[4] at the Drug De-addiction & Treatment Center (DDTC), Department of Psychiatry, Postgraduate Institute of Medical Education and Research, Chandigarh, India comprising 80 men of Opioid dependence , this sample size is exactly similar to our study and revealed that age range of 17-50 years, mean was 30.17±7.00 years. **Om Prakash Giri et al**[5] **(2013)** conducted a study at De-addiction Centre of tertiary care hospital at BHU, Varanasi and reported the mean age of Opioid dependent as 36 years.

Similar to our findings, **Kumar N et al**[6] **(2013)** reported mean age of the patients was 41.9 years in patients attending De-addiction Centre in South India and nearly one-third of patients (31.3%) were aged between 31 –40 years.

Table No. - 1 Socio-Demographic Profile Of Opioid Dependence Patients.

		MMT		BMT			
Age	Age group	N =40	%	N=40	%	N=80	%
	20 to 30 year	8	20	13	32.5	21	26.25
	31 to 40 year	14	35	16	40	30	37.50
	41 to 50 year	10	25	8	20	18	22.50
	51 to 60 year	6	15	3	7.5	9	11.25
	61 to 70 year	2	5	0	0	2	2.50
	Mean Age	40.4±11.30		35.6±9.26		38±10.60	
Religion	Hindu	25	62.5	30	75	55	68.7
	Muslim	15	37.5	10	25	25	31.3
Domicile	Urban	33	82.5	35	87.5	68	85.0
	Rural	7	17.5	5	12.5	12	15.0
Marital status	Married	30	75	27	67.5	57	71.25
	Unmarried	10	25	13	32.5	23	28.75
Education status	Up to 10th	34	85	39	97.5	73	91.25
	More than 10th	6	15	1	2.5	7	8.75
Employment status	Employed	5	12.5	3	7.5	8	10.0
	Unemployed	7	17.5	6	15	13	16.25
	Labor	28	70	31	77.5	59	73.75
Family type	Nuclear	25	62.5	29	72.5	54	67.50
	Joint	15	37.5	11	27.5	26	32.50

The majority (71.25%) of patients were married, if we compare both groups 75% were married in MMT and 67.5 married in BMT group **(Table 1)**. **Biswajit de et al**[4] revealed that marital profile was 50% never married, 47% married and 3% divorced among Opioid dependent patients. Similar findings were also reported by **Kumar N. et al**[6] **(2013)** and **Shahrokh Aghayan et al**[7] **(2018)** who revealed that majority of substance abuse patients attending De-addiction Centers were married (74.7% & 82.5 % respectively).

If we classify the smack dependent patients according to their religion, it was found that majority of the patients (68.8%) were Hindus and 32.3% were Muslims **(Table 1)**. Similar findings were also reported by **Bichitra N Patra et al**[8] **(2015)** who conducted a study in de- addiction centres of tertiary care general hospitals in North India, found that higher percent of Hindus were taking Opioid (52%) . This fact may be possible due to preponderance of Hindu community in our country. **Biswajit de et al**[4] revealed that 56% were Hindus and 44% were Sikhs, this difference was due to prevalence of Sikhs community in Haryana and Punjab region.

If we classify patients according to domicile status majority (85%) of patients were from urban background with 82.5% patients from MMT group & 87.5% patients from BPMT group **(Table 1)**. The reason for higher prevalence of heroin dependence in urban population may be due to easy and wide availability of heroin through various sources in urban areas as compared to rural areas. Also, MMT & BMT is given on daily basis, so for rural patients it may not be easy to come daily for Opioid substitution therapy in de-addiction centre, which are situated in urban locality, due to lack of easy transportation and distance of de-addiction center.

Majorities (91.3%) of substance users in our study were educated up to 10th standard and remaining 8.8% were having higher education **(Table 1)**. This finding can be explained by the fact that people who were illiterate or having low education were usually not aware of adverse effects of these illegal substances and thus were easy target for drug peddlers. A study conducted our neighboring state Haryana in Rohtak **by Viney Kumar et al**[9] **(201 3)** revealed that higher proportion of substance abuse patients belongs to lower education groups.

If we classify patients according to their occupation, it was evident that 73.75% of patients were from the labor class (skilled or unskilled) who earn their livelihood on daily wages basis. If we compare both groups it was evident that in MMT group 70 % were from labor class and in BPMT group 77.5% patients belonged to labor class **(Table 1).** Persons from labor class are primary target for drug peddlers. This fact can be explained as opium reduces pain sensitivity and labor class population seeks for various self medicating strategies to reduce pain like analgesics, opium, etc. so they are prone to opium addiction.

If we compare both MMT and NOMT groups according to their family type, it was evident that the majority i.e. 62.5% of MMT and 72.5% of BPMT group belonged to the nuclear family **(Table 1)**. People living in joint family have less chances of having drug abuse, because of family restrictions & social norms. In nuclear family mostly the person himself is head of family, where he doesn't have familial restrictions. Similar findings were also reported by **Kumar N et al**[6] **(2013)** that the majority of patients (77%) belonged to nuclear families.

The mean age for initiation of opioid intake in our study was 24.93 years. If we compare both MMT and BMT groups, BMT group had early initiation than MMT group and this difference was statically significant **(Table 2). Biswajit de et al**[4] conducted a study to determine age of onset in Opioid dependent men and revealed the age 13-39 years with mean age 23.06 years.

Table No. 2 Comparison Between Age Of Initiation Of Opioid In MMT & BMT Group.

Mean age of Initiation in years	Methadone	Buprenorphine	t	P value
	27.98	21.88	3.744	< 0.01
	24.93			

Our findings of socio-demographic profile is similar to previous Indian studies like **Ambekar A et al**[10] **(2015)** who conducted a survey on 3620 patients of opioid dependence in Punjab and revealed that about 76% opioid dependent individuals were in the age group of 18 to 35 years, about 99% were males, 54% were married, 89% were literate and most of them were employed and their major occupations were: unskilled worker/ laborer (27%); farmer (21%); clerical jobs/ businessmen (15%); Transport worker (14%) and skilled worker (13%).

Likewise **A.M. Kadri et al**[11] **(2003)** studied the socio-demographic profile of 560 substance abusers attending de-addiction centres in Ahmedabad city and revealed that majority (46%) of them were in the age group 26-35 years and 46.4% of them had started taking drugs before the age of 20 years. Findings of these studies are almost similar to our study which was conducted in northwestern part of India.

In India family members take the primary responsibility of care. After marriage, spouse is directly involved in the care of partner and can be considered as primary caregiver. In the present study all patients were male and we chose wife, sibling, mother, father and son as a primary caregiver among all family members. In our study 65.% were wives, 20% were parents, and 6.2% were their child, and 8.8% brothers as primary caregivers **(Table 3)**.

Table No. 3 Distribution Of Caregiver According To Relationship.

Relationship	N	%
Wife	52	65
Siblings	7	8.8
Mother	14	17.5
Father	2	2.5
Son	5	6.2

If we compare quality of life in patients of opioid dependence, patients on Methadone maintenance **(MMT)** treatment showed better quality of life as compared to that in Buprenorphine maintenance therapy **(BMT)**. QOL in all four domains (physical health, psychological health, social relationship & environmental health) was better in **MMT** than the **BMT** group & this difference was statically significant (P< 0.05) **(Table 4)**.

Table No. 4 Comparison Of QOL Scores Between BMT & MMT Patients.

Quality of Life	BMT	MMT	P -value
Physical health	62.8	68.4	0.038*
Psychological health	56.03	63.88	0.004*
Social relationship	51.83	52.15	0.915
Environmental health	58.20	62.48	0.082

Burden score in all five domains was less in **MMT** group than **BMT** group and this difference was statistically significant in all domains. Caregivers of patients on BMT perceived less severity of burden as compared to the caregivers of MMT **(Table 5)**.

Table No. 5 Comparison Of Burden Scores Between BMT and MMT Patients.

Burden on care giver	Buprenorphine	Methadone	Correlation
Impact on well being	7.70	5.38	0.001
Impact on marital relationship	6.48	3.83	0.001

Appreciation of care giving	7.50	5.90	0.001
Impact on relation with others	7.78	5.03	0.001
Perceived severity of disease	7.30	5.43	0.001

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