

EXTRA MURAL RESEARCH

Double blind placebo controlled trial of Homoeopathic medicines in the management of withdrawal symptoms in Opium addicts and its alkaloid derivatives-dependents

Ajay Grover, Bharat Bhushan & Rajesh Goel

Navjyoti Drug Demand Reduction Training Institute, New Delhi

Objectives: To ascertain the efficacy of Homoeopathic medicines in the management of withdrawal symptoms in Opium addicts & its alkaloid derivatives-dependents.

Methods: 169 patients addicted primarily to opium, its alkaloid derivatives either natural or synthetic (Morphine, Codeine, Heroine, Pethidine and other Narcotic etc.) were enrolled for the study between September 2002 to August 2005. Only male patients within 15 – 50 yrs of age coming to the O.P.D. were admitted and included in the study. The study was conducted at Navjyoti Drug Demand Reduction Training Institute, New Delhi. Indicated homoeopathic medicines (on the basis of characteristic symptoms of each medicine) out of the selected six useful medicine was prescribed to manage withdrawal symptoms experienced by the enrolled patients. The medicines and placebo were coded. Approximately half of the patients were given medicines & other half received placebo. Assessment of progress made in each individual symptom was recorded for both the groups.

Results: Action of medicines & placebo in relieving the withdrawal symptomatology of Opium Drug Dependents was recorded from 3rd day onward after starting the treatment. The action of each individual Homoeopathic Medicine in relieving symptoms is significantly better than that of placebo in each group in this study.

Conclusion: Homoeopathic medicines have acted better in relieving the acute withdrawal symptoms than the placebo in each group. Symptoms like lachrymation, sneezing, yawning, abdominal pain, constipation, anxiety & irritability have particularly responded better to the medicine than placebo.

Key words: opium dependence, abstinence syndrome, withdrawal symptoms.

Introduction

Role of homoeopathic medicines in the withdrawal symptoms of Drug Dependents (*Opium & its alkaloids derivatives-dependents*) is very significant as has been observed by clinical experience of over 14 years of Navjyoti Drug Demand Reduction Training Institute. Homoeopathic medicines were effective in the treatment of withdrawal symptoms of Drug Dependents (Opium & its alkaloids derivatives-dependents)¹. Out of these six most efficacious homoeopathic medicines were selected for double blind placebo controlled trial in this project to further evaluate their role in the management of withdrawal symptoms¹.

The withdrawal symptoms of opium & its alkaloids derivatives-dependents consist of lachrymation, bodyache, pain in legs, rhinorrhoea, sneezing, yawning, vomiting, nausea, diarrhoea, abdominal pain, loss of appetite, chill, piloerection, heat alternating with chill,

sleeplessness, restlessness, anxiety & irritability etc^{2,3,4}. The withdrawal symptoms usually develop 8 to 16 hrs. after the last dose of opium & its alkaloids derivatives consumption².

Objective

To ascertain the efficacy of Homoeopathic medicines in the management of withdrawal symptoms of *Opium & its alkaloid derivatives-dependents*.

Material and Methods

169 male patients between the age group of 15 years to 50 years, addicted primarily to opium, its alkaloids derivatives either natural or synthetic (Morphine, Codeine, Heroine, Pethidine and other Narcotic etc.) reporting the O.P.D. at Navjyoti (new patients or referred by Govt. hospital, NGOs, Social worker and physician, through social worker and awareness program) were enrolled and admitted for the study in the IPD.

* Address for Correspondence:

Dr. Ajay Grover

Navjyoti Drug Demand Reduction Training Institute
Khasra No. 99, Karala Majri, Delhi - 110081

Routine investigations which included Chest x-ray, Hb, TLC, DLC & ESR were advised for all the patients taken into the study.

Patients with Co-existent active tuberculosis or any other chronic illness were excluded.

Case recording and prescription making

The physician recorded the case history by filling up the pre-designed case-record form inquiring into the drug abuse history, pre morbid personality, past treatment, personal history and family history of the patient. Full general and systemic examination of the patient were carried out and recorded.

Patients were asked about their presenting complaints. As most of the cases were asymptomatic on the first day of admission (because of the last dose of drug taken on the same day), the symptoms of abstinence developed on the second day. Patient's withdrawal symptoms were carefully noted down with respect to location, sensation, modality and concomitants.

After analysis with Mac Repertory Software, indicated medicine from selected group of six medicines namely Arsenic album, Nux-vomica, Ipecac, Chamomilla, Rhus tox, Pulsatilla was prescribed.

The recording was done regularly on day-to-day basis for 30 days. It was ensured that the patient was maintained in the original group through out the study and does not cross over to the other group.

Potencies & Dosage

Homoeopathic medicines were prescribed in potentized form in sugar cane globules (30 No. Size). 4 globules constituted a dose. Medicines were procured from a reputed pharmaceutical of the same batch number for the whole project duration. 30th potency of the medicine was used four times in a day for each patient.

The medicines were dispensed from the coded bottles of these six homoeopathic medicines. We had six bottles of each medicine numbered 1 to 6 in pills (of size 30) of 30 potency. For each medicine out of these 6 bottles only 3 contained medicine & other 3 had placebo. Indicated Medicines were dispensed from these bottles. In this way half of the patients actually received placebo.

Coding of Medicine

The coding was done by Central Council for Research in Homoeopathy (CCRH).

Grouping

Half of the patients were kept as control (85 on drug and 84 on placebo). Patients were divided as per Randomization table provided by CCRH.

Follow-up

The follow up of the each patient with respect to each symptom was done on day-to-day basis for the first 30 days.

Observations

Maximum number of patients were in the age group of 15 to 30 years in each group. (Table 1)

62 percent of patients had addiction from one to five years. (Table 2)

Table 1: Age Group

Age Group	Number of Patients Enrolled on Control	Number of Patients Enrolled on Medicine Group
15-20 yrs.	16	15
21-25 yrs.	24	25
26-30 yrs.	16	15
31-35 yrs.	07	08
36-40 yrs.	06	06
41-45 yrs.	06	07
46-50 yrs.	09	09
Total	84	85

Table 2: Period of Addiction

Period of Addiction	Number of Patients Enrolled on Control	Number of Patients Enrolled on Medicine Group
01-05 yrs.	53	51
06-10 yrs.	20	22
11-15 yrs.	05	06
16-20 yrs.	04	05
21-25 yrs.	02	01
26-30 yrs.	–	–
Total	84	85

Results

169 patients were enrolled for the study as per the inclusion criteria. All 169 patients were dispensed medication from the pre selected group of six efficacious medicines as per the indications.

After decoding, it was found that 85 patients

received the actual medicine and 84 patients received the placebo (Table-3).

Results of both the medicine and the placebo groups were compared for disappearance of symptoms after the 3rd day of starting the treatment. The difference in the number of patients relieved by the third day was compared for each of the 19 symptoms. (Table No. 4).

Table 3: No. of Patients enrolled under each group of medicine & placebo

Name of the Medicine	Total No. of Patients	Total No. of Patients on placebo	Total No. of Patients on Medicine
Arsenic album	66	33	33
Nux vom	38	19	19
Rhustox	35	17	18
Pulsatilla	19	10	9
Ipecac	6	3	3
Chamomilla	5	2	3
Total no. of patients enrolled	169	84	85

Table-4

S. No.	Symptom	Under Medicine		Under Placebo		P-value
		No. of patients with symptoms	No. of patients relieved and Percentage	No. of patients with symptoms	No. of patient relieved and Percentage	
1	Lachrymation	63	48(76.1%)	62	37 (59.6%)	0.047
2	Bodyache	63	31(49.20%)	62	26(41.93%)	0.41
3	Pain in Legs	65	24(36.92%)	62	24(38.70%)	0.85
4	Rhinorrhoea	43	36(83.72%)	47	34(72.34%)	0.19
5	Sneezing	45	28(62.22%)	45	16(35.55%)	0.011
6	Yawning	64	42(65.63%)	67	28(41.79%)	0.0062
7	Vomiting	15	12(80%)	16	14(87.5%)	0.46
8	Nausea	28	25(89.28%)	30	24(80%)	0.27
9	Diarrhoea	32	24(75%)	29	17(58.62%)	0.173
10	Abdominal Pain	42	30(71.42%)	40	20(50%)	0.046
11	Loss of Appetite	41	27(65.85%)	43	22(51.16%)	0.17
12	Chill	54	31(57.40%)	55	24(43.63%)	0.15
13	Piloerection	41	28(68.29%)	43	25(58.13%)	0.33
14	Constipation	26	24(92.30%)	26	14(53.84%)	0.0017
15	Heat alt. With Chill	12	11(91.66%)	10	8(80%)	0.42
16	Sleeplessness	66	31(46.96%)	66	21(31.18%)	0.07
17	Restlessness	66	35(53.03%)	72	27(37.5%)	0.0669
18	Anxiety	38	30(78.94%)	42	25(59.52%)	0.06
19	Irritability	26	22(84.61%)	23	11(47.82%)	0.0061

Discussions

It is important to note that this study evaluated the six most efficacious homoeopathic medicines namely Arsenic album, Nux-vomica, Ipecac, Chamomilla, Rhus tox., Pulsatilla on a double blind placebo controlled design in treating the withdrawal symptoms in Opium addicts and its alkaloids derivatives-dependents.

A sample size of 169 patients was taken to ensure sufficient number of patients in each group so that the study could be evaluated as per the standard statistical analysis.

The study reveals that out of these six medicines four medicines namely Arsenic album, Nux-vomica, Rhus tox, Pulsatilla appear more frequently indicated. Based on the findings of the study, *Arsenicum album*, *Nux vomica*, *Rhus tox.*, and *Pulsatilla* are found to be effective in the management of withdrawal symptoms in Opium & its alkaloid derivatives-dependents.

It has been observed that different symptoms have responded differently to the action of medicines.

It has been observed that medicines have acted better in comparison to the placebo group in relieving the symptoms like Sneezing, Yawning, Abdominal pain, Lachrymation and Irritability having statistical significant *p value* of less than 0.05 (Table 4). Sleeplessness, Restlessness and Anxiety have also responded better with the medicines in comparison to the placebo group as is supported by the statistical analysis having *p values* around 0.06 (Table 4). The analysis was done utilizing chi square test/Fisher's exact test by using EPI INO packages.

The Chi Square analysis of each individual symptom was done to know the significance of difference in the action of medicines and placebo. Analysis of individual symptom has shown that medicines have acted significantly better than the placebo in relieving some of the acute manifestations of withdrawal like sneezing, yawning, abdominal pain, irritability, lachrymation, sleeplessness, restlessness and anxiety.

In symptoms like bodyache, pain in legs, rhinorrhoea, vomiting, nausea, diarrhoea, abdominal

pain, loss of appetite, chill, piloerection and heat alternating with chill, it was observed that the proportions of symptoms relieved in placebo and medicinal group are not statistically significant. It also indicates that these symptoms have not responded to medicine.

Conclusion

It is concluded that Homoeopathic Medicines have significantly acted better than the placebo group for managing withdrawal symptoms in Opium & its alkaloids derivatives-dependents.

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