Pacini Editore & AU CNS

HEROIN ADDICTION & RELATED CLINICAL PROBLEMS
www.europad.org

Regular article

Heroin Addict Relat Clin Probl 2008; 10(1): 13-18

First Experience of Opioid Therapy with Buprenorphine in Ukraine

Sergey Dvoryak and Irina Grishayeva

Ukrainian Institute on Public Health Policy, Kiev, Ukraine

Summary

Ukraine is the country that has the highest rate of HIV/AIDS among IDUs in Europe. The development of opioid maintenance treatment for opioid users is an important public health issue.The earliest utilization of buprenorphine for OMT was made in 2004-5, within the framework of the UNDP Applied Human Rights Project. It was accompanied by research which was a part of the WHO Collaborative Study on Opioid Treatment of Opioid Dependence and HIV/AIDS. There were 67 opioid drug users under observation. This was a prospective observational study with assessments at baseline, and at 3- and 6-month follow-ups. All assessments refer to the period of one month prior to interview. The main aims of outcome evaluation were to explore changes in the following domains: health status and well-being of individuals in opioid treatment; community/social benefits and also programme performance. Improvements in the main indicators were documented after 6 months of treatment. The retention level was 66% and the mean buprenorphine dose was about 8 mg/day. The main conclusion is that buprenorphine treatment is effective in the context of Ukrainian social conditions.

Key Words: Opioid Maintenance Therapy; Treatment; Opioid Dependence; Buprenorphine

1. Introduction

During the last decade Ukraine has experienced a remarkable increase in opioid addiction. Most addicts are young people still living with their parents; their addiction problem has lasted a few years. According to the Ministry of Health data, about 96% of those suffering from addictive disorders are intravenous opioid users. At the end of 2004 there were close to 88,000 registered drug addicts in the country. But this figure reflects only those who went to narcology institutions to ask for medical help. The estimated number of the whole IDU population in Ukraine is about 450,000 (937.5 on 100,000 of population). Most of these people live in big cities and are aged between 20 and 29. IDUs still constitute a major part of PLHA. IDUs who are living with HIV/AIDS have no access to effective treatment for their addiction or somatic disease because of the lack of funds, the poor education of staff and double stigmatization. Besides, a drug treatment is an effective way of preventing HIV, as has been shown by many researchers all over the world.

IDUs accounted for 70% of HIV cases in the Ukraine between 1987 and 2004. In 2005, Ukraine was home to the fastest growing HIV epidemic in Europe, and one of the fastest growing epidemics in the world (Report of the Global HIV/AIDS Epidemic, 2002; UNAIDS/WHO 2005). With a growing HIV epidemic among opioid-dependent injectors, the need for both prevention

Correspondence: Sergey Dvoryak, MD, Ukrainian Institute on Public Health Policy, Kiev, Ukraine 53/30 Bozhenko Str., Apt 15 Kiev, 03150 Ukraine
Tel.: +38 044 537 6415. E-mail: dvoryak@uiphp.org.ua

and treatment of opioid dependence, as well as HIV, became apparent. Drug treatment using opioid therapy (OT) was recognized to be indispensable in bringing opioid-dependent substance users into treatment, and so reducing the overall frequency of injection-related risk-taking behaviour. In addition, it was believed that OT would allow for those already infected with HIV to access life-saving anti-retroviral therapy (ARVs), which had previously been denied to them.

At the beginning of 2004 there were still no OT programmes in Ukraine. In the process of implementing the Applied Human Rights project, the UNDP was faced with the need to provide OT pilots to allow IDUs the highest possible level of physical, mental and social well-being.

UNDP-Ukraine decided to carry out two pilot projects in Kherson and Kiev with the aim of launching a model of opioid therapy for IDUs in the country in 2004. Buprenorphine was chosen as a replacement drug, as methadone was not yet available, and serious political and public resistance was directed against it. According to Ukrainian legislation, buprenorphine could only be used in a medical setting under the direct observation of medical staff. That meant that there was no opportunity to use take-home doses. Clients received buprenorphine every day; on Sunday only, they were given a double dose. Special premises were organized where clients took medication under medical control, and there were other rooms where they could spend their time and receive counselling.

2. Methodology

As for buprenorphine opioid therapy, we used the recommendations of R.Johnson (2001), E.Strain (2001) and Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (2004).

Pilot projects in Kherson and Kiev were accompanied by thorough observation according to the WHO standards. It was organized within the framework of the WHO Collaborative Multisided Study "Opioid Treatment of Drug Dependence and HIV/AIDS". The methodology of the study was worked out by WHO experts R. Ali (Adelaide University, Australia) and A. Uchtenhagen (Zurich University, Switzerland). All the clients were tested by diagnostic instruments at the beginning of treatment and after 3 and 6 months. The following research tools were used: for the evaluation of Individual Health Status and Well-being – Addiction Severity Index (ASI), Opioid Treatment Index (OTI), Zung Depression Scale, WHO Questionnaire of Quality of Life (WHOQOL), blood-born virus risk-taking behaviour indicator (BBV-track); for the evaluation of Community/Social benefits – criminal involvement indicator (OTI, section 2).

3. Sample demographics

3.1 Sample description.

The total number of individuals participating in the study was 76 – 26 in Kherson and 50 in Kiev.

The mean age of participants at entry was 30.6 (range 47-21) – 33.5 for Kherson and 29.1 for Kiev. Participants were mostly males (90%) – 96% in Kherson and 86% in Kiev. The total number of females recruited for the programme was only 8.

Most of the participants had never been married (42%). 17% are currently married and 20% are cohabiting. 16% are divorced and 5% are widowed or married, but now live without a partner.

The median number of sexual partners at entry to treatment was 1; this figure stayed unchanged throughout the duration of the study (range 3-0).

Mean years of completed education is 12.6 (range: 19-8). In Ukraine basic school education lasts 9 years.

75% of the study participants are living in their own homes (or the homes which belong to their family). 23.6% are renting either an apartment or a room, and 1.3% (1 person) has no fixed address.

3.2 Clinical parameters

Among others, two of the basic criteria for inclusion in the programme were: a minimum of 2 years of problematic opioid drug use and several periods of unsuccessful drug-free treatments received by an individual.

The most common type of opioid drug first used is poppy straw (or so-called 'home-made opium') – 60% (77% in Kherson and 52% in Kiev). 16% of participants used heroin as their first opioid drug (24% in Kiev and none in Kherson). 24% of all the participants used other types of opioids (tincture of opium, morphine, acetylated opium solution).

Mean age at first opioid usage was 18.5 (range 33-14). Thus the group of people in the study included both: more common cases of early drug use debut and less common cases of a late debut (up to 33 years). Figures for this variable show no differences between Kiev and Kherson.

Mean years of problematic drug use at entry turned out to be as follows for different substances (mean ± st. deviation; range):

- Alcohol: 13 ± 7 (range: 33-0);
- Other opiates/analgesics: 10.3 ± 6 (range: 33-0);
- Barbiturates: 0.7 ± 2.4 (range: 16-0);
- Other sedatives/hypnotics/tranquillizers: 1.05 ± 2.5 (range: 16-0);

- Amphetamines: 0.2 ± 0.75 (range: 5-0);
- Cannabis: 6.6 ± 6.9 (range: 27-0);
- Cocaine: 0.05 ± 0.28 (range: 2-0).

For these variables, the figures for Kiev and Kherson do not differ.

As the reported data show, the most common problematic drugs are opiates, cannabis and alcohol. The prevalence of opiates is logical, considering the type of treatment received by the patients. Cannabis and alcohol are very common substances in Ukraine, in general.

As a rule, people involved in the study have previously used various types of drug dependency treatment. The following figures show the percentage of individuals who used the indicated type of treatment at least once in their lifetime.

Each of the figure in brackets shows the maximum number of treatment episodes for a single individual (minimum is 0 in each case).

- Inpatient detoxification: 70% (Max # of treatment episodes: 20);
- Outpatient detoxification: 60% (Max # of treatment episodes: 20);
- Outpatient counselling: 48% (Max # of treatment episodes: 40);
- Residential rehabilitation: 34% (Max # of treatment episodes: 12);
- Methadone and other opioid pharmacotherapy: 3% (Max # of treatment episodes: 6).

For the baseline interview, the following data were reported about drug use during the previous 30 days (mean ± st. deviation; range):

- Alcohol: 7.53 ± 8.13 (range: 30-0);
- Heroin: 0.52 ± 1.5 (range: 8-0);
- Other opiates/analgesics: 11.47 ± 11.9 (range: 30-0);
- Other sedatives/hypnotics/tranquillizers: 1.4 ± 5.5 (range: 30-0);
- Amphetamines: 0.61 ± 3.7 (range: 30-0);
- Cannabis: 6.32 ± 8.2 (range: 30-0);

For other opiates and cannabis the differences between the two cities are quite substantial (opiates: 26 ± 7.5 for Kherson and 4.2 ± 4.7 for Kiev; cannabis: 4.3 ± 8.1 for Kherson and 7.3 ± 8 for Kiev).

The mean severity of dependence (SDS score) at entry into treatment was 10.97 ± 2.7 (range 15-5), where 8% of individuals reported a score of 0-5, 32% a 6-10 score, and 60% an 11-15 score. The data obtained show that the severity of dependence is, on average, rather high for each of the groups under study. The differences recorded between the two cities did not reach significance.

The mean number of physical symptoms (OTI section 3) at baseline was 18.8 ± 8.4 (range 39-2), (13 ± 7.1 for Kherson and 21.7 ± 7.5 for Kiev).

Mean psychological morbidity indicator (Zung score) at baseline was 46.11 ± 11.3 (range 74-21), where 58% reported 49 or less (likely not depressed), 40% reported in the 50-69 range (likely to be mildly depressed), and 2% reported 70 or more (likely to be moderately to severely depressed). The differences between the two cities did not reach significance.

The average daily buprenorphine dose at entry into treatment was 13 ± 5.4 (range 30-2), (9.12 ± 5.1 for Kherson, and 14.4 ± 5.02 for Kiev).

4. Key Results

3- and 6-month follow-up interviews were conducted only for those individuals who were still in the programme, so the number of cases analyzed for the 3-month follow-up was 54, and for the 6-month follow-up was 50.

The average daily buprenorphine dose at the 3-month follow-up was 7 ± 4.4 (range 20-2), (without significant differences between Kherson and Kiev). At the 6-month follow-up, it was 5.5 ± 3.2 (range 18-2), (7.1 ± 4 for Kherson, and 4.6 ± 2.2 for Kyiv).

There were no significant differences in indicator variables between individuals who received prescriptions for relatively high and relatively low doses of buprenorphine(for more or less than 8 mg/day throughout the period of study).

Paired t-tests were used to verify the hypothesis of no difference in the values of variables from baseline to the 3-month follow-up and from the 3-month to the 6-month follow-up.

4.1 Outcome evaluation

4.1.1 Individual Health Status and Well-being

The substance use fell significantly (P<.05) after 3 and after 6 months compared to baseline. The average number of days out of the previous 30 when an individual had used a substance is the following:

- Alcohol: after 3 months 2.32 ± 4.7 (range: 30-0), after 6 months 1.4 ± 2.15 (range 7-0);
- Heroin: 0 both for 3- and 6-month follow-ups;
- Other opiates/analgesics: after 3 months 0.02 ± 0.132 (range: 1-0), after 6 months: 0;
- Other sedatives/hypnotics/tranquillizers: after 3 months 0.18 ± 1.3 (range: 10-0), after 6 months: 0;
- Amphetamines: 0 both for 3- and 6-month follow-ups;
- Cannabis: after 3 months 1.77 ± 6.9 (range: 30-0), after 6 months 0.66 ± 1.9 (range 10-0).

The differences between the two cities are only significant (P<.05) for alcohol usage (greater in Kher-

Table 1. Self-perceived quality of life indicator (WHOQOL) for baseline, 3-month follow-up and 6-month follow-up.

	Baseline	3-month follow-up	6-month follow-up
Domain 1	44.8 ± 17 (range 81-6)	60.8 ± 17.6 (range 100-19)	73 ± 11.7 (range 88-25)
Domain 2	44.08 ± 18.2 (range 75-6)	62.6 ± 13.17 (range 94-19)	69.7 ± 9.2 (range 81-25)
Domain 3	45.4 ± 20 (range 100-0)	55.25 ± 15.3 (range 94-25)	52.4 ± 11.5 (range 81-0)
Domain 4	50.3 ± 15.36 (range 94-25)	60 ± 13.7 (range 88-25)	67.6 ± 11.12 (range 94-31)

son).

The mean number of physical symptoms (OTI section 3) at the 3-month follow-up was 4.35 ± 3.3 (range 18-0), (no significant differences between the two cities). At the 6-month follow-up: 2.63 ± 3.9 (range 24-0), (4.45 ± 5.8 for Kherson and 1.5 ± 1.14 for Kiev).

Both from baseline to after 3 months and from after 3 to after 6 months, the decrease was statistically significant (P<.000).

At the 3-month follow-up, the mean psychological morbidity indicator (Zung score) was 37.76 ± 11.78 (range 69-21), (the difference between cities was not significant). At the 6-month follow-up: 29.13 ± 7.2 (range 53-22), (31.75 ± 10 for Kherson, and 27.5 ± 4.7 for Kiev).

Both from baseline to after 3 months and from after 3 to after 6 months, the decrease was statistically significant (P<.000).

The following table represents the Mean ± StD (range) for self-perceived quality of life indicator (WHOQOL) for baseline, 3-month follow-up and 6-month follow-up. The indicator is divided into 4 domains.

Both from baseline to after 3 months and from after 3 to after 6 months, the increase is statistically significant (P<.01). The exception is the 3- 6-month decrease for Domain 3, which is not statistically significant.

Table 2 represents the Mean ± StD (range) for the blood-born virus risk-taking behaviour indicator (BBV-traq) for baseline, 3-month follow-up and 6-month follow-up. The indicator is divided into 3 sections: Injecting practices, Sexual practices, and Skin penetration.

The reported figures for the section "Sexual practices" were significantly higher in Kiev (compared to Kherson) for all 3 interviews. For the two other sections, the differences between the two cities did not reach significance.

From baseline to after 3 months, the decrease is statistically significant (P<.05).

From after 3 to after 6 months, the difference is not significant.

As no testing for blood-born infections was done during the study, is is impossible to report the prevalence of BBV.

4.1.2. Community / Social benefits

At baseline the percentage of employed individuals was 45%. At the 3-month and at the 6-month follow-ups, the figure was 14% and 54% respectively. However, only 20 (3-month) and 12 (6-month) individuals answered this question during follow-up interviews.

Mean value (range) of the criminal involvement indicator (OTI, section 2) was as follows (the differences

Table 2. Blood-born virus risk-taking behaviour indicator (BBV-traq).

	Baseline	3-months follow-up	6-months follow-up
Injecting practices	12.8 ± 14.15 (range 59-0)	1.04 ± 5.8 (range 42-0)	0.68 ± 4.9 (range 36-0)
Sexual practices	11.14 ± 9.5 (range 36-0)	7.6 ± 7.9 (range 27-0)	8.34 ± 7.4 (range 27-0)
Skin penetration	1.81 ± 2.5 (range 8-0)	0.15 ± 0.63 (range 3-0)	0.11 ± 0.47 (range 3-0)

between the two cities were not significant):
- Baseline: 1.6 ± 2 (range 7-0);
- 3-month follow-up: 0.02 ± 0.134 (range 1-0);
- 6-month follow-up: 0.

From baseline to 3 months the decrease is statistically significant (P<.000).

From 3 to 6 months the difference did not reach significance.

4.1.3. Programme performance

Of the initial total of 76 individuals involved in the programme, 54 (71%) were retained in treatment after 3 months and 50 (66%) after 6 months.

The respective rates for Kherson only were 77% / 73%; for Kiev only, they were: 68% / 62%.

Only those receiving opioid treatment (as a drug) were interviewed after 3 and 6 months.

5. Conclusion and recommendations

- Buprenorphine is effective for Opioid Maintenance Treatment (OMT) in terms of: reduction of opioids, other illicit substances and alcohol use; improvements in health status and quality of life; reduction of depression; reduction of risky behaviour; decrease in criminal involvement;
- The most dramatic changes were recorded in the three months following the initiation of treatment;
- In the stabilization phase, buprenorphine was effective at a dose of ~ 8 mg/day, and even less;
- The retention in treatment level was 66%; this must be considered a very good indicator for treatment programmes in Ukraine;
- OMT should be recommended in Ukraine and expanded rapidly.

Role of funding source

UNDP - Ukraine

Contributors

The authors contributed equally to this work.

Conflict of Interest

The authors have no relevant conflict of interest to report in relation to the present study.

Acknowledgments

We want to thank Dr. A.Viyevskiy (Chief-Narcologist of the City of Kyiv), Dr. I. Garkusha (Chief-Narcologist of the Kherson Region), Dr. A. Podsvirova (Kyiv) and Dr. I. Blizhevskaya (Kerson).

References

1. REPORT OF THE GLOBAL HIV/AIDS EPIDEMIC, GENEVA, UNAIDS, 2002. http://www.unaids.org/Unaids/EN/Resources/Publications/Corporate+publications/Report+on+the+global+HIV_AIDS+epidemic+2002+.asp
2. UNAIDS/WHO, AIDS EPIDEMIC UPDATE: December 2005 http://www.unaids.org/epi/2005/doc/report_pdf.asp
3. ROLLEY E. JOHNSON, ERIC C. STRAIN, LESLIE AMASS. Buprenorphine: How to Use It Right. Department of Psychiatry and Behavioral Sciences Johns Hopkins University School of Medicine and Friends Research Institute, Inc., Los Angeles, California
4. ERIC C. STRAIN, JEANNE G. TRUMBLE, GAIL B. JARA. Use of Buprenorphine in the Pharmacologic Management of Opioid Dependence. A Curriculum for Physicians. January 2001 www.nida.nhi.gov
5. CLINICAL GUIDELINES FOR THE USE OF BUPRENORPHINE IN THE TREATMENT OF OPIOID ADDICTION. Laura McNicholas, Conses Panel Chair. A Treatment Improvement Protocol 40. DHHS Publication No. (SMA) 04-3939 Printed 2004. US Department of Health and Human Services. SAMHSA. Center for Substance Abuse Treatment.

Received October 19, 2006 - Accepted February 14, 2007


SAVE THE DATE
EUROPAD forum
during
AATOD
Conference
new york city
2009
APRIL 25 - 29, 2009
HILTON NEW YORK
www.aatod.org