

# Program of the University Clinic of Toxicology, Skopje, Republic of Macedonia in Treatment of Drug Addiction (Buprenorfin Treatment Protocol)

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## PROFESSIONAL PAPER

### SUMMARY

The program of our Clinic includes, not only treatment of acute intoxication with opioids and other drugs, but also comprehends clinical investigations and treatment of the somatic complications of this population. For the first time in our country our Clinic offers to this population the alternative way of treatment with Buprenorfin. The Clinic started with this protocol on August 1, 2009. During a period of two years, the treatment with Buprenorfine has been initiated in 353 patients, of which 211 regularly attend the medical check ups. This model is used according to the national clinical guidelines and procedures for the use of buprenorfine in the treatment of opioid dependence. The dose of this medicament depends on the evolution of the withdrawal symptoms. We have used the objective and subjective opioid withdrawal scale for the observation of these symptoms (OOWS ; SOWS – Handelsman et al 1987). This protocol starts with a complete clinical investigations, (i.e. where all patients undergo the inclusion and exclusion criteria with a written consent). Afterwards, the patients are hospitalized and start with a Buprenorfin treatment. After period of 7-10 days hospitalization they come to our Clinic, like outpatients for a regular controls. We have precise evidence for every patient who comes for control (e.g. medical record with all biochemical and toxicological screenings). All patients are recommended a tight cooperation with psychiatrists who are specialized to treat the problematic drug addictions.

**Key words:** Buprenorfin, opioid addicts, national guidelines, withdrawal scales.

## 1. PROGRAM IN TREATMENT OF DRUG ADDICTION (BUPRENORFIN TREATMENT PROTOCOL)

Nowadays, the number of drug addicts in our country increases. Beside the programs of methadone in our country, our Clinic developed own program and organization in treatment of opioid addicts. The Clinic of Toxicology offers to the drug addicts the following program:

### 1.1. Complete clinical investigations

- Laboratory analysis (blood test, complete enzyme status, glicemia, degradation products, protein status, bilirubins, electrolytes, lipid, immune, urine status and, if it is necessary, additional more specific laboratory investigations);
- twelve-channel electrocardiogram;
- ultrasound examination of the abdomen;
- toxicological screenings;
- Serological investigation (virus hepatitis A, B, C and HIV virus);
- Other necessary investigations;

### 1.2. Treatment of acute somatic complications and tight cooperation with the other health organisations

- Treatment of acute intoxications with opioids and other drugs
- Treatment of withdrawal syndrome
- Treatment protocol (Buprenorphin)
- Educational schools

Recently the Clinic has been actively involved with its own lectures in prevention of the drug abuse in primary and high schools through the Agency of Sport and Youth (the lectures are performed continuously)

In addition to the prevention, the Clinic of Toxicology in future plans to organize educational center for the existing addicts, our patients. Lectures in educational center will be organized once per month in the Clinic of Toxicology upon prior appointment. The working groups will be consisted of not more than five members. The education will be conducted in presence of the addicts' close family members. The purpose of this education is to familiarize the addicts with the serious, eventually possible somatic health problems as a result of the long-term drug application. The lectures will be conducted by the experts of the Clinic of Toxicology and

eventually from the other clinics. The Program will cover the most common diseases that might affect the health of the addicts (hepatitis, thrombophlebitis, endocarditis) and it will be realized through short lecture about the topical disease, presentation of personal experiences, questions by the addicts and their family members and answers of the experts.

## 2. NURSE CARE IN BEHAVIORAL PROBLEMS

- Be persistent and keep up the level of attitude and behavior that you expect from the patient, do not argue with the patient;
- Confront with the patient trying to persuade him/her that that is not a good idea;
- Pay attention to patient who shows specific behavior: for ex. discusses, shows feelings, anger;
- Talk with the patient without judgemental tone;
- Be kind with the patient, but restrained;
- Set a clear border-line and make the patient be aware that you care for his/her well being

The Clinic started with treatment of the opioid addicts with the medication with generic name Buprenorfin on 1 August 2009.

The approach towards these patients is multidisciplinary and goes through several phases. Prior the detoxification, the patients are subjected to informative talk/discussion for the purpose to evaluate the motivation of the patient for detoxification, family support and to explain the protocol of detoxification development. The patients are enrolled in this treatment in accordance with strictly determined inclusive and exclusive criteria, and upon detailed clinical examination of patients and writtning the consent for voluntary admission and request for detoxification with the medication. (1) Buprenorfin and compliance to the rules and regulations of the Institution.

At the beginning the treatment takes place in hospital where the patients are received on the Department of Intensive Care and Department of Detoxification of the University Clinic of Toxicology on seven to ten-days treatment.

Upon completion of hospital treatment, daily visits are scheduled in the ambulance department of the University Clinic of Toxicology where rigorous medical check ups are conducted for the patients that attend regular check up visits. The medication is not used only in hospital treatments but also in long-term detoxification whereas the medical check ups include regular toxicological screenings of the Forensic Medical Institute, biochemistry analysis of the Biochemistry Clinic, close cooperation with Clinic for infective diseases, for virus-infected patients and regular check ups of psychiatrist.

Having in mind that the opioids addicts are population at risk of other diseases as well (inflammatory processes, vascular disorders, hepatitis and so on) often there is a need of other medications that in most of the cases are hepato-protective therapy, antibiotics, analgetics and etc. The selection of other therapy is under strict indication with great caution for eventually possible synergy with the

effects of the Buprenorfin medication.

## 3. CRITERIA FOR ADMISSION OF THE PATIENTS IN THE PROGRAMME

- Patients above 18-years of age with symptoms of opiate withdrawal syndrom, who are physically addicted of opioids and need withdrawal syndrom treatment;
- Patients who fulfill DSM-IV criteria for opioid addiction;
- Systole blood pressure  $\geq$  100mg Hg and pulse  $\geq$  56 pulse/min;
- Overall good health condition;
- Capable of signing/accepting Consent of Protocol approved by the Institutional board and Consent of parent/guardian
- Compulsory use of contraceptive methods by the female-patients enrolled in the study
- Buprenorfin must be used with caution with patients suffering from: asthma or respiratory insufficiency; kidney and liver failure; (2)

## 4. CRITERIA FOR NON-ADMISSION OF THE PATIENTS IN THE PROGRAMME FOR DETOXIFICATION

- History of significant violent behavior;
- Schizophrenia or considerable mood changes (depression);
- Acute serious psychiatric condition and condition of threatening suicide;
- Addiction of alcohol, benzodiazepine or other depressors or stimulants;
- Clinically significant deviation of the ECG;
- Participation in detoxification method with methadone (above 30mg per day) or LAAM (above 40mg for 48 hrs);
- Lack of ability to remain in the Institution where the detoxification program takes place during the active phase of the treatment (3)

## 5. CRITERIA FOR TERMINATION OF DETOXICATION

- Medical record for use of opioids during the detoxication program;
- Non-compliance to the rules and regulations of the Institution in accordance with the signed Consent for medical treatment, signed upon admission;
- Occurrence of serious side effects; (4)

*The Protocol of detoxication with Buprenorfin goes through several stages (TIP 40)*

Induction day;

Stabilization phase;

Maintenance phase;

Evaluation of symptoms is rated through subjective scale and objective scale rating symptoms of withdrawal syndrome (5)

In dependence of the development speed and intensity

of the symptoms of the withdrawal syndrome, the patient is gradually prepared for treatment with buprenorfin.

Treatment with Buprenorfin usually starts 10-12 hrs after the last application of heroine, and approximately 24 hrs after the last dosage of methadone. Initial starting dosage of Buprenorfin is 2 mg, and maximum dosage until the end of the first day is up to 8 mg.

On the second day of the started treatment the patient is observed and the patient is given the total dosage from the previous day. If the patient feels well, the dosage has been stabilized. But if the intensity of the withdrawal symptoms is stronger, on the second day the dosage could be increased up to maximum 16 mg, and on the third day up to 32 mg.

In the upcoming days the dosage is stabilized and eventually corrected in order to reduce the withdrawal symptoms, before the patient is released from the Clinic. (6)

Upon release the patient is advised to attend regular check up visits where depending on the patient's condition, the dosages are gradually decreased until final termination (individually at each patient).

## 6. METHOD OF PRESCRIPTION OF BUPRENORFIN

Buprenorfin is medication in a format of a tablet with dosage of: 0.4 mg, 2 mg, 8 mg and it is only administered sublingually.(7) It can be prescribed in hospitals (under supervision of medical personnel) and outpatients (in ambulance);

For outpatients it is foreseen:

- Daily administration of Buprenorfin (daily regime) and
- Preparation for take-home medication

### 6.1. Daily administration (in cases when the patient is not escorted)

During the whole medical treatment (short and long treatment), opioids drug addicts are required:

- To attend daily the medical institution during the whole medical treatment
- To take the medication in front of the member of the medical personnel
- To adhere to the Consent Protocol Agreement and to actively participate in the medical treatment;
- Twice per month to attend medical test for presence of drugs and other substance in the urine;

### 6.2. Buprenorfin Take-Home Medication

Upon a decision of the medical team and as token of trust and support for the patients for the achieved positive changes in realization of the agreed medical treatment, the medication is prepared and given to be consumed at home, in dependence of the opioid drugs. It is foreseen to prescribe

the Buprenorfin once per week for take-home medication. The prescribed dosage is taken only in front of the parent/guardian, spouse. The prescribed dosage is collected by the parent/guardian, spouse.

- To adhere to Consent Protocol Agreement and actively participate in the medical treatment;
- Twice per month to attend medical test for presence of drugs and other substance in the urine;

During a period of two years, the treatment with Buprenorfin has been initiated in 353 patients of which 211 regularly attend the medical check ups. Since July 2010 the costs for Buprenorfin program are covered for the most motivated patients by the Government of the Republic of Macedonia. The costs related to Buprenorfin are covered for 140 patients with tendency to increase. So far four patients have successfully completed the treatment protocol with Buprenorfin. Clinic of Toxicology develops a strategy to cover with Buprenorfin a part of the prisoners who fulfill criteria for admission of the patients in this protocol.

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