

MEDICALLY ASSISTED TREATMENT FOR OPIATE ADDICTION - SUBOXONE METHOD AS PREVENTION OF SOCIAL EXCLUSION OF YOUTH – TUZLA MODEL

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SUMMARY

Aim: To present medically assisted treatment for opiate addiction with substitution medicament Suboxone and prevention of social exclusion of young opiate addicts in Bosnia and Herzegovina.

General overview: Until recently there was no solution for long-term and comprehensive treatment of young persons who suffer from opiate addiction. This is not an illness that impairs only psychological and physical health of addicts with possible fatal aftermaths, but serious societal problem due to its consequences such as delinquency, crimes and violence that lead young people to social exclusion. There are no capacities within the existing health facilities for long-term stationary treatment, which is necessary for drug addiction. In addition, far less adequate solution is placement of young addicts into penal and correctional institutions, which are stigmatizing and contribute to their exclusion from normal social life.

Hence, the latest medically assisted method of substitution treatment with a combination of buprenorphine and naloxone (Suboxone) is introduced. This medicament, with its characteristics, offers possibility for outpatient treatment, and prompt and effective results of detoxification and weaning of opiates is to be achieved. Opiate addicts that undergo this treatment benefit from "clear mind" and capability for occupational and social activities, which significantly improves the quality of their family and social relations. With Suboxone substitution method, the institutional (inpatient) treatment is to be avoided and social exclusion of young addicts treated with Suboxone prevented.

Conclusion: Medically assisted treatment for opiate addiction with Suboxone is conducted in outpatient setting with the involvement of close relatives who are not addicted. It brings back "clear mind" to previous addicts, does not stigmatize but contribute to re-socialization and prevention of social exclusion of young opiate addicts.

Key words: opiate addiction - substitution therapy - medically assisted treatment – suboxone - social exclusion - Bosnia and Herzegovina

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INTRODUCTION

It is known that substance abuse is a severe disorder with harmful effects to psycho-physical health of its users, which are often fatal (such as HIV/AIDS, hepatitis B and C, a death from overdose or other life endangered circumstances in which users are brought into searching for psychoactive substance). It imposes a substantial burden on society that is forced to suffer the aftermath of addictive behavior, delinquency and violence (Hasanović 2001, Hasanović et al. 2012c). The existing health facilities are not able to provide long-stay in stationary institutions, which is necessary for drug addiction treatment, while correctional institutions and prisons are not an adequate solution to this problem for in most cases the consequences of addictive behavior onto society are only delayed that way (Hasanović 2002). Therefore, medically assisted maintenance method for treatment of opiate addicts with a combination of buprenorphine and naloxone (Suboxone) is introduced at the Department for Psychiatry of the University Clinical Center (UCC) Tuzla in July 27th, 2009, with consent of management of UCC Tuzla, Institute for Health Insurance of Tuzla Canton (ZZOTK) and Ministry of Health of Tuzla Canton. This method was developed into a unique concept called

"Tuzla's Treatment Model for Opiate Addiction with Suboxone", adapted to existing social condition and financial circumstances (Hasanović et al. 2011). At the meeting between the Minister of Health of Tuzla Canton in presence of the Interior Minister of Tuzla Canton and his spokesman, the Director of the Health Center Tuzla and his Deputy, General Director and Medical Director of the UCC Tuzla and Director of the ZZOTK, and representatives of the Department of Psychiatry, it was decided that Suboxone can be prescribed only by licensed specialists in neuropsychiatry upon approval by the Minister of Health of TK.

This method ensures that young people return to a healthier lifestyle from the beginning of their treatment. Also, they are able to give in return to community much more than it was invested in the treatment, in contrast to patients whose disease despite a high quality treatment ended with permanent disability, inability to operation and the maintenance and death (Demetrovics et al. 2009). Also, it is discussed in this paper that the treatment of heroin addicts is not just a job of psychiatrists and the Department of Psychiatry. What is needed is a complex synchronized and phase-defined action of all segments in the community, which should contribute through the three levels of prevention of drug addiction (Hasanović 2001, Hasanović & Hasanović

2001). With this method we are offering the arguments to resist and successfully cope with this past daunting social and medical evil (Hasanović et al. 2012).

We would like to emphasize that all addicts enrolled in this program are treated by only two specialists in neuropsychiatry beside their regular work at the Department.

EXPERIENCES OF THE STAFF INVOLVED IN THE TREATMENT OF OPIATE ADDICTS USING SUBOXONE

In 2002 the Department of Psychiatry of the University Clinical Center Tuzla, Bosnia and Herzegovina, established a close and fruitful international collaboration with „Beroendecentrum“, the Centre for Dependency Disorders of the Örebro University Hospital in Örebro, Sweden. Through this collaboration our doctrine has been updated on the basis of experiences and latest world's achievements applied in Sweden. In January and February 2005, the two experts in this field from our Department went for study tour to Örebro Centre for Dependency Disorders where they have acquired theoretical and practical knowledge about the usage of buprenorphine in opiate addicts treatment. In March 2005 buprenorphine was added to the World Health Organization (WHO) Essential Medicines List, and since January 2007 it was added in Croatian Essential Medicines List.

In December 2007 Suboxone is registered in Federation of Bosnia and Herzegovina (B&H). At its 66th session held in 19 August 2008, the Federal government adopted a decision to add Suboxone pills on the Essential Medicines A List necessary for the provision of health care within the standards of the mandatory health insurance in Federation of B&H. When an authorized distributor got a drug in its warehouse in 27 July 2009, a new method of opiate addiction treatment became available in the Department for Psychiatry in Tuzla. Determined to help addicts and their families, we suggested to begin with the administration of substitution therapy if they agree to buy medicine until it is redeemed for the Essential Medicines A List and a special doctrine for its legislation and prescription developed by the Institute for Health Insurance of Tuzla Canton.

Thanks to the unquestionable consent of addicts and their families interested in, a gradual admission to treatment with Suboxone begun based on our own doctrine, which was established in respect to the realistic circumstances of an addict way of life, our working conditions at the Department along with a strict adherence to medical principles and legal regulations.

The doctrine is based on the following principles:

1. *Maximum level of drug control;*
2. *Elimination of all patterns of addictive behavior;*
3. *Partnership with family members of psychoactive substance addicts;*

4. *Reliable coordination with the pharmacy;*
5. *Detection and treatment of HIV, Hepatitis B and C;*
6. *Detection and treatment of dual diagnosis;*
7. *Knowing of the trials and penal measures, and assisting the addicts in maintaining his or her new lifestyle and behavior while serving their sentences.*

The ultimate goal is to enable an individual to achieve lasting abstinence without substitution and rehabilitated and resocialized to continue more healthful lifestyle (Maremmani & Gerra 2010).

Ad 1.

Since the administration of substitution therapy with Suboxone begun before the ZZO TK adopted the doctrine of its administration, the addicts paid for the drug until 17 February 2010, when the ZZO TK in agreement with the Minister of Health, the management of the University Clinical Center Tuzla, and Department of Psychiatry, officially accepted very efficient, newly established model that was developed based on the latest theoretical and practical achievements (Demetrovics et al. 2009).

After a detailed medical evaluation and psychosocial preparation of an addict, along with establishing collaboration with her/his parents and/or spouse or significant other that is not addicted, a consilium specialists that lead the expert team of our Department decide of the introduction of opiate addict to treatment program with Suboxone. If the members of the consilium find no contraindications for this treatment option, an addict and her/his partner in the treatment who is not addicted (parent, spouse or significant other) sign the contract with consilium, which regulates that Suboxone pills will be taken regularly, in proper dosage, in a prescribed manner, and that it won't be misused or alienated any of the tablet with an awareness of the criminal responsibility for interrupting treatment and illegal distribution of pills.

Thereafter an addict and her/his treatment partner sign an informed consent to medical conditions of treatment, which regulates the strict abstinence of illegal psychoactive substances, as well as of alcohol and benzodiazepines, which in case of its simultaneous use represent a fatal complication of the treatment with Suboxone. The informed consent is also signed by the president of the consilium with a guarantee for regularity of drug administration according to the doctrine. The contract created in this way represents an official document signed by three parties about obligations and rights of drug addict, her/his family/significant other, and professionals as service providers. All data is kept in the system and stored within the medical records.

Prescriptions are prescribed in two copies only by two specialists psychiatrists from the Department of Psychiatry (currently Dr. A. Kuldija and Prof. M. Hasanovic), authorized by the Ministry for Health of Tuzla Canton, Institute for Health Insurance of Tuzla

Canton (ZZO TK), University Clinical Center Tuzla and Department for Psychiatry, who have their own coded stamps entered in the upper right corner of the prescription. Prescriptions are verified by the doctor with his signature and stamp on its back too. Only one pharmacy in Tuzla Canton is authorized for Suboxone procurement, where the signatures and signed copies of an informed consent of addicts and their treatment partners are being deposited. The manager and the pharmacy staff closely cooperate with specialists in case of any ambiguities, inconsistencies or doubts about possible misuse of prescriptions. According to the doctrine adopted in Tuzla Canton, the Institute of Health Insurance of Tuzla Canton provides up to 8 mg of Suboxone daily per addict for free, while the rest of dosage, if needed (daily dose over 8 mg) is self-paid. The costs of Suboxone purchase from 27 July 2009 to 17 February 2010, in a period prior to doctrine guidelines development, were reimbursed (part of the cost up to 8 mg) by the cantonal health system.

Female addicts begin treatment with a gradual introduction, controlling withdrawal for at least 24 hours after the last intake of opiate, starting with 4 mg sublingually. The dose is titrated during an emergency period of no longer than four days. On the fourth day most addicts are generally stable, clear-minded, doing well and continue on a steady dose taken on the 4th day. In the following one-month period the patient must visit the doctor on a limited basis - once a week- when urine screening is used and, if negative, the new prescription is prescribed. From then, the patient is assessed every 28 days and urine screening is mandatory (opiates, BZD and other psychoactive substances).

Ad 2.

The patients are asked to stop taking all PAS (including benzodiazepines and alcohol) due to their possible fatal complications. Treatment should not be initiated if the patient is positive to substances other than opiate. If the addict is smoking, then he or she is being motivated to cease cigarette smoking. They are offered substitution therapy with Nicorette chewing-gum, which contribute to reduction of overall addictive behavior and the promotion of healthy lifestyle.

Ad 3.

Due to a broken family relations in the family of addicts, the non-addicted family members are very interested in the treatment of addiction.

Seems to be glad to get involved through a partnership (e.g. to pick-up medication at the pharmacy, to come to see a doctor together with a patient, to control taking pills at home and to observe their behavior.

This model of treatment brings several benefits.

- Family psycho-education is included in our intervention (information about PAS and substance abuse are provided to non-addicted family members).

- The stigma is reduced or eliminated as well as the fear of this disease. Initially, it is profoundly important for establishing trust in relationship between family members and addict who begins to heal.
- No longer need to look for a daily dose of opiates and for the money that he or she must have to get it. Now, the patient stays at home, sober and of good behavior, prepared for the activities within the family that one had previously avoided.
- The treatment partner is directly controlling taking pills, which support renewal of the forgotten emotional binds between "parent and a child."
- The appetite improves and the patient gain in weight, while the whole family is having meal together their relationships improve too.
- The addict is forbidden to behave improperly, to take pills on their own, and no offence is to be made. If this happens, a partner in the therapy is obliged to report to the physician in order to detect and mediate in problem solving.
- The patient is prohibited to possess a Suboxone pill. Having Suboxone in a pocket is considered to be possession with the intent to distribute. According to the agreement with a police, if this is a case, it is treated as a serious offense that must be reported and prosecuted (Hasanovic et al. 2012).

Ad 4.

There is a telephone connection with the pharmacy authorized for Suboxone procurement and its distribution. In case of any doubts, the pharmacist makes a phone call to physician in charge of prescription to check details. If anything wrong is detected, medication distribution is stopped, while patient and treatment partner are referred back to physician in charge to correct mistake. The medication can not be distributed to anyone before a signed copy of documentation about regular introduction to treatment based on our doctrine is submitted. It provides the maximum level of distribution control from the pharmacy, preventing drug to be available on the black market.

Ad 5.

Before the addict is considered for substitution treatment introduction, a candidate is obliged to do regular serological testing for HIV, HBV and HCV (Hasanović et al. 2012b) through a strict laboratory procedure required in our doctrine. If the person is positive to HIV, Hepatitis B and/or Hepatitis C, she or he is referred to the specialist for infectious diseases and hepatologist to perform a gene typization of virus and to begin an adequate antiviral therapy. Representatives from the Department for infectious diseases, Department for Internal diseases and Department for Psychiatry made a protocol of collaboration ensuring that these patients are treated from the infectious disease, which is result of intravenous opiates administration using non-

sterile needles. Since neuropsychiatrists are physicians in charge for introduction and addiction treatment, and additionally trained in psychotherapy, it is easy for them to detect psychological difficulties that arise in persons who began treatment with interferon, thereby quickly and properly react in time. It is known that intravenous opioid addicts with comorbid Hepatitis C who undergo simultaneous treatment of both conditions are not prone to relapse (Hasanović et al. 2012b).

Ad 6.

Introduction to substitution treatment with Suboxone helps in solving problems that resulted from opiate abuse, and then basic problems related to dual diagnosis appear. These are mainly presented with depression or psychotic equivalent or uncontrolled aggression that have been invisible while the person was taking drug regularly. A proper medication and psychotherapy are offered in the recovery process, which proved to be of help.

Ad 7.

Our treatment model is also available for opioid addicted prior to and while serving a prison sentence. A collaboration is established with prison staff who are in charge of medication, urine screening and escorting the patients to a regular medical assessment every 28 days.

Since 27 July 2009 to present we have successfully introduced to treatment the 159 (one hundred fifty nine) opiate addicts from several cantons of the Federation of Bosnia and Herzegovina, and several places from Republic of Srpska. One addict coming from Serbia (Valjevo) also begun with our treatment program, of which he is fully-charged being a foreign national. According to our monthly report in August 2012, the 117 persons are enrolled in treatment. Eight of them who broke the rules of treatment were temporarily excluded from the program, and after repentance and promises to adherence to treatment they were introduced again, following complete introduction procedure (laboratory and serological testing) and signing an informed consent.

Out of 42 persons who are out of program now, 11 recovering addicts ceased use of the drug and move into drug-free recovery and normal life (Hasanović et al. 2012a). Two patients from Sarajevo who were introduced to our program continued their treatment in Sarajevo. One patient continued his substitution therapy in Austria where he resides, but he was introduced to our program during holidays he spent in B&H.

Another one from Breko District ceased use of the drug due to a lack of finance, and his insurance does not cover the treatment in the Federation of B&H. One patient emigrated to Denmark in order to avoid serving a prison sentence.

The others stopped treatment due to various forms of violation of treatment contract that they willingly signed. Some of them often committed crimes, including drug trafficking, and several of them are prisoners now.

Our work is also focused on psychotherapy model that will help overcoming psychological complaints and the reasons for relapse. Our goal is to support rehabilitation and resocialization of all opiate addicts, to help them to increase the level of their social functionality and to achieve drug-free recovery.

Total amount of Suboxone, monthly and single daily dose during the period January-May 2012 are shown in the table 1.

As above presented it is evident that a daily dose per patient was from 7.2 mg (March 2012) to 7.8 mg (April 2012), and most common daily dose of 7.7 mg for the remaining three months. Knowing that the recommended daily dose of Suboxone may be from 4mg to 32 mg, our patients successfully maintained remission and abstinence < 1/4 of maximum dose (32 mg), which is considered to be an excellent result.

On the other hand, if we take into consideration:

- That each young people, while taking heroin, spent app. 25 Euros for illicit drug(s) supply; when we start to treat them, each of them have been moved from the street(s), not taking part in drug trafficking in an amount of app 750 Euros per person. When multiplied it with a number of treated addicts with buprenorphine/naloxone, this figure increases hundred times. It means that the black market is loosing 75,000 Euros monthly and about 900 000 Euros annually.
- It is stated that in U.S., 1 US \$ invested into heroin addiction is saving 10 US \$.
- With this treatment, they returned to their homes, continued life in their regular emotional and social roles, such as: being sons and daughters of their parents, spouses of their partners, parents of their children and friends.
- Those who have hepatitis C or B, are detected and involved in the treatment procedure with interferon, which prevents later complications of liver disease and premature death.

Table 1. Prescribed amounts of Suboxone and a single daily dose during the period January-May 2012

Month	Patients from TK/ mg per patient	mg	Patients out of TK	mg	Total number of patients	Total milligrams
January	99/7.7mg	23.526	6	1.130	105	24.836
February	95/7.7mg	21.328	6	0.928	101	22.256
March	104/7.2mg	23.094	6	1.240	110	24.334
April	99/7.8mg	23.096	7	1.208	106	24.304
May	102/7.7mg	24.250	7	1.488	109	25.738

- They will not experience and die due to "overdose".
- They won't steal and distribute drug(s) in order to provide "a daily dose of opiates" that they need to survive somehow with no withdrawal.
- Those who are in trial or already prosecuted to serving a prison sentence, have a chance to continue the treatment in prison, which is supporting the abstinence and safety that they will not return to addiction and crime.
- If employed, they successfully return to their occupational roles. If unemployed, they are seeking for a regular job on the labor market.
- Three patients had entered university and study while taking suboxone.
- Ten of them got married after introduction substitution treatment, having their wives as partners in the treatment process. Based on our doctrine, the medication is taken daily at home in the presence of treatment partner, who is carefully monitoring his/her partner and regularity of treatment.
- A certain number of addicts successfully completed treatment and continued normal drug-free life.

We would like to point out that in current context of health care policy, we are spending a lot of money for the treatment of different diseases using expensive methods and medicaments while results of these treatments are inefficient.

SUBOXONE – AN EFFECTIVE BUPRENORPHINE/NALOXONE COMBINATION

Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Suboxone is a combination of buprenorphine to which antagonist naloxone is added to reduce the likelihood of content and abuse of intravenous administration of dissolved tablets. When taken sublingually, buprenorphine acts but Naloxone does not work and there has been a therapeutic effect achieved. But if Suboxone tablets are crushed and injected subcutaneously or intravenously, the effect of naloxone antagonist is overridden, causing withdrawal symptoms, in the addictive jargon known as "night time", so that addicts do not want to take it improperly, and the abuse is prevented.

According to benefit-cost analysis of opioid addiction treatment with buprenorphine and methadone, the annual treatment costs per addict in Croatia covered by health insurance are reduced twice if buprenorphine is used (Čulig & Sakoman 2005) (Table 2).

Table 2. Illustration of Annual Costs of Opioid Treatment in Croatia

Medicine	Total Annual Costs of Opioid Treatment per Addict in Croatia covered by Health Insurance (Kn)
Buprenorphine	5.550,00
Methadone	10.734,00

In the Italian analysis of the costs of buprenorphine vs methadone treatment of opiate addicts the results show that with the same action and even higher market price of buprenorphine, the latter represents a cheaper alternative of addiction treatment for the society due to shorter duration of treatment and especially flexible regime of administration (a patient is rarely coming to addiction center than in case of methadone treatment) (Colombo et al. 2003).

Suboxone therapy resulted in a significant drop in the number of deaths associated with the use of medicine compared to methadone, and ten times lower number of deaths from opiate overdoses. Suboxone does not lead to the development of tolerance (no need for a constant increase in dose); it is far less addictive, and better tolerated than methadone known to cause serious cardiac arrhythmias, particularly in drug addicts with previous heart disease, disorder of mineral/salt metabolism or impairment of liver function. Also, the interruption of Suboxone therapy, if necessary, is much less complicated. This "smart drug" has far fewer interactions with other drugs compared to methadone. Also, it reduces the possibility of illegal use unlike methadone. It is helping us to support the patient to become distant from addictive surroundings. Suboxone diminishes their stigmatization, it is well suited for take-home medication, which significantly reduces the presence of patients/addicts in the waiting rooms of health facilities as well as the need for alternative treatment in so-called social institutions/communities. It is important to emphasize that the patients taking Suboxone at home have three times greater chance of employment than those involved in methadone programs. Students who interrupted their study due to opiate dependence, returned to university while in Suboxone treatment reporting on Suboxone to "clear their mind". Some of those admitted to Suboxone therapy, who did not study previously, became interested in applying and successfully enrolled in university (Ling et al 2010, Wesson & Sith 2010).

Suboxone is well suited for home use, and may be prescribed to the new patients, patients who are returning to a treatment program and those switching from other therapies. The experiences of institutions dealing with Suboxone treatment have shown that this is the safest and most cost-effective treatment option for opiate/heroin addicts. If therapy process is well implemented, a reconstruction of the brain function, the personality development and the improvement of the overall living conditions of addicts and their families is achieved in time.

In comparison with methadone treatment, Suboxone has an advantage for after the maintenance program on an adequate daily dose, the overall capacity of drug addicts is increasing, and therefore he or she has a better chance for successful and complete quitting, maintaining abstinence without any medicine (Kakko et al. 2007). Methadone more often induces tolerance, with an

increasing dose of the drug required, leading to more severe clinical presentation. Therefore, after a few years despite the wish of an addict to detoxify, the chances for the establishment and maintenance of abstinence are lowered.

CONCLUSION

With introduction of medical model of substitution therapy for opiate addiction in 27 July 2009 at the Department for Psychiatry of the University Clinical Center Tuzla, we provide a new doctrinal approach that proved to be very effective. This model and approach ensure the maximum control of the drug, the elimination of almost all patterns of addictive behavior and partnership with non-addicted family members, reducing or eliminating stigma, making sobriety a way of life, and preventing social exclusion through rehabilitation and resocialization. Establishing reliable coordination with pharmacy supports the maximum control of drug trafficking. Furthermore, this approach helps in detection and treatment of dual diagnosis and referral of HIV, hepatitis B and C patients. Knowing of the trials and penal measures to be taken, in collaboration with staff of correctional institutions this framework is assisting addicts in maintaining his or her new lifestyle and behavior while serving their sentences. The method also provides future admission to treatment of a greater number of opiate addicts caught in a trap of complex, multi-layer dependence and its somatic and psychosocial complications caused by long-term addictive and criminal behavior.

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