A Clinical Study on an Acute Therapy for Recovering the Normal Physiology in Narcotists using Tuo Yin Tang Jiang made of Chinese Medical Herbs

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Abstract

Narcotic drugs generally refer to serious and habitual hidden rash such as opium, heroin, methyphetamin, nabinol, cocaine, and so forth. At present, narcotic drugs are spread unchecked and are causing a big social problem. So many countries and narcotists are making every effort to set up a barricade against narcotic drugs. And there is a limit suitable treatment for them. Thus Tuo Yin Tang Jiang is developed.

As indicated by Chinese letters, Tuo Yin Tang Jiang(**TYTJ**) is a crude drug. It is a traditional chinese medicine developed by the study done from June in 1998 to June in 1999 that Hubeisheng was entrusted with by People's Republic of China. This study is a treatise on etiology and syntomatology of narcotism. TYTJ is a medicine which is in accord with Pharmacopeia of the People's Republic of China[1)] in order to remove from the body the toxic materials resulting from narcotic drugs such as opium and heroin.

According to the standard diagnosis on narcotism, 105 cases are studied and treated at the Rehabilitation Center attached to Enshi Autonomous Region Hospital in Hubeisheng.

105 cases are divided into 2 groups by double-blind method. One is the experimental group which has 56 cases. The other is the control group which has 49 ones. 13 cases among 105 cases are addicted by intravenously injections. 9 cases are by oral takings. It took 10 days for this experiment to be performed. Two groups didn't show a striking individual variation based on the age, gender, period of taking drugs, withdrawal symptoms, complication, and state of health.

The experimental group had a higher effect of treatment than the control group had. TYTJ treats diseases effectively and has no side effect, irrespective of the serious or slight addiction to opium and morphine.

Ⅰ. Introduction

According to the standard diagnosis on narcotism, 105 cases are studied and treated at the Rehabilitation Center attached to Enshi Automous Region Hospital in Hubeisheng.

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II. Definition of Narcotism and its Diagnostic Standard

According to Jin Du Quan Shu[2], a complete book of anti-toxication, abusing narcotic drugs satisfy the following items;

1. to take narcotics for more than a month
2. to reach the habitual state of taking narcotics everyday and not to be able to stop taking them or to reduce the quantity of them
3. to reach the state of not leading a normal life at home, work, and school and much less committing social crimes.

If there is a person satisfying 3 items above, the person is diagnosed as the addict.

The diagnostic standard of narcotism is the following;

1. The above-mentioned 3 items are fully satisfied.
2. The addict increases a dose in quantity because of the drug-induced tolerance.
3. If the addict do not take narcotics, he or she will have withdrawal symptoms.

If 3 items above are satisfied, it is diagnosed as narcotism.

The following 11 items show symptoms.

1. Lacrimation.	2. Foul Nasal Discharge.	3. Mydriasis
4. Keratosis Pilaris	5. Diarrhea	6. Hidrosis
7. Yawning	8. Secondary Hypertension	9. Tachycardia.
10. Fever	11. Insomnia	

If more than 4 items are satisfied at the same time, it is diagnosed as withdrawal symptoms.

The standard of recovering the normal physiology is the following;

1. not to take narcotics for treating period
2. not to show withdrawal symptoms for 5 days when stopping taking

medicine or not to agree on the above-mentioned 3 items which are diagnosed as narcotism

3. to gain weight and take meals normally

III. An Acute Therapy for Recovering the Normal Physiology and Recent Situations

At present, many countries use a treatment of drug, a sealed containment, and a psychological treatment in parallel.

The addict often hurts himself or herself because of not overcoming withdrawal symptoms easily. For this reason the addict had better be blocked.

A psychological treatment helps the addict to overcome withdrawal symptoms, to recover the normal physiology, and to get out of the psychological state of dependence on narcotics by encouraging the addict's self-pride and self-respect.

At present a disposition of drug is composed of a substitutional therapy, a treatment of degradation, and a supplementary treatment.

A substitutional therapy is a way of substituting weak narcotics for strong ones. For example, we can use methadone[3], morphine, dihydroetorphine, and buprenorphine as a treatment because they have weak poison relatively. But they are apt to induce drug tolerance, if the patient takes them for a long time. So he or she has serious side effect, and falls into drug habituation.

A treatment of degradation is a way of degrading the poisonous effect by using alexpharmacons, cycloxoine, naloxone, clonidine[4], and naltrexon e, which are antagonists against narcotics. But if it takes long to treat the addict, he or she gets poisoned because he or she is exposed to side effect resulting from the use of antagonists, and seriously shows adverse reaction and withdrawal symptoms. Thus these can not be used as a medical

treatment for a long time.

A supplementary treatment is a temporary way of treatment in accordance with progressive symptoms and cannot control withdrawal symptoms.

A disposition of drug cures the addict of addicted symptoms and helps him or her to recover the normal physiology. But it has the limits as follows;

1. We are lacking in medicines to modulate and alleviate withdrawal symptoms.
2. We have no effective way of treating psychological dependence. So the patients are likely to abuse narcotics again.

Ⅳ. A Diagnosis of Traditional Chinese Medicine(DTCM) and Bian Zhe Lun Zhi(BZLZ) : A Selection of Treatment Based on the Differential Diagnosis.

BZLZ is one of the most essentials to traditional chinese medicine[5], which makes a diagnosis of the disease (known as Bian Zheng) based on the analysis and comprehension of the symptoms and body conditions by the four methods of examination, the eight principal syndromes, the viscera and meridians, the etiology and pathogenesis, and formulates definitive therapeutic programs on the basis of this(known as Lun Zhi).

The addict get damaged to Yuan Qi(Primordial Energy), according to DTCM[6], who falls into QiXu(Deficiency of Qi), whose symptoms are characterized by shortness of breath, spontaneous sweating, palpitation, dizziness, lassitude, inertia, poor appetite, losing weight, and getting emaciated. The male addict has nocturnal emission and impotence. The addict has feeble and weak pulse, or the addict has feeble and large pulse on releasing but weak pulse on pressing[7].

Therefore according to DTCM, TYTJ is developed to invigorate Qi and remove toxic materials.

V. How to Make an Experiment.

1. The Classification of the Experimental Group and Treatment

Both TYTJ and Tramadol & Diazepam which are supplementary drugs were prescribed for the experimental group to overcome withdrawal symptoms. Based on the seriousness or slightness of withdrawal symptoms, TYTJ ranging from 50ml to 200ml was given to the experimental group three times a day.

As a supplementary treatment, if the patients have the symptom of arthralgia of extremities, they orally take Tramadol or get an intramuscular injection of Tramadol ranging from 50mg to 100mg each time. If they suffer from insomnia, they take Diazepam(7-chloro-1-methyl-diazepinone, Valium), and get anintramuscular injection of Diazepam ranging from 10mg to 20mg each time.

2. The Control group and Treatment

Methadone, khellidine, and capsules of Shen Jin Dan which is chinese herbal medicine, were prescribed for the control group to overcome withdrawal symptoms. Tramadol and Diazepam as a supplementary treatment were prescribed. During a sealed containment, no medicine was prescribed.

The addicts got an intramuscular injection of Methadone ranging from 10mg to 50mg each time. They did 3 times a day. In 3 or 5 days they got an intramuscular injection reduced by 20%. Between 15 and 20 days they didn't get.

They took 2 to 3 tablets(one tablet contains 0.2mg of Khellidine) each time. They did one or two times a day. Between 7 and 10 days no tablet was prescribed.

Capsules of Shen Jin Dan[8] which had been used before TYTJ is developed were given to the patients 4 times on the first day. Their dosage was 5 to 6 capsules. On the second day 4 capsules were given 4 times. On the third day

3 capsules were given 3 times. Fom the fourth day on, 2 capsules were given 3 times. Between 8 and 10 days no capsule was given.

Capsules of Shen Jin Dan are a medicine already prepared by a pharmacy. They are a crude drug which is made of Lumbricus[9], Semen Strychni, Flos Carthami, Carterii, Myrrha, Rhizoma Drynariae, Cortex Acanthopanacis Radicis. and Radix Stephaniae Tetrandre[10].

As indicated by Chinese letters, Tuo Yin Tang Jiang(TYTJ) is a crude drug. TYTJ is made of Radix Condonosis Pilosulae, Radix Astragali seu Hedysari, Radix Aagelicae Sinensis, Poria, Bulbus Fritillariae Cirrhosae, Bulbus Allii Macrostemi, Fructus Corni, Fructus Amomi, Fructus Crataege, Fructus Ziziphi Jujubae, Folium Nelumbinis, Stamen Nelumbinis, Cortex Eucommiae, Cortex Moutan Radicis, Semen Euryales, Pericarpium Citri Reticulatae, Rhizoma Zingiberis Recens, Rhizoma Pinelliae, Rhizoma Dioscoreae, Rhizoma Gastrodiae, Rhizoma Cimicifugae, Rhizoma Alismatis, Flos Caryophylli, etc.

It is a traditional chinese medicine developed by the study done from June in 1998 to June in 1999 that Hubeisheng was entrusted with by People's Republic of China. This study is a treatise on etiology and syntomatology of narcotism. TYTJ is a medicine which is in accord with Pharmacopeia of the People's Republic of China in order to remove from the body the toxic materials resulting from narcotic drugs such as opium and heroin.

Both the experimental group and the control group had no medicine to overcome withdrawal symptoms from a week ago before doing this experiment to the end of the experimental period. For 10 days the groups were observed and medicines were prescribed. In 24 hours, 48 hours, 72 hours, 5 days, and 10 days two groups were observed and compared.

3. An Observation of the Efficacy of a Medicine.

The efficacy of medicine is based on it that 11 withdrawal symptoms are alleviated and disappeared, or the normal physiology is recovered, or the

patients gain weight.

4. Observational Level and Method

The withdrawal symptoms, the adverse reaction, and the change of the patient's weight were observed. Generally the withdrawal symptoms and the adverse reaction are classified into five ranks as follows according to Jine Du Quan Shu[2](P577~P578) ; Table 1.

Table 1. Observation of Withdrawal Symptoms

Rank	Withdrawal Symptoms
Level 0	Yearning for the inevitableness, Terrible anxiety
Level I	Yawning, Hidrosis, Lacrimation Foul Nasal Discharge, Fatigue.
Level II	Pupillary Mydriasis, Tabescentium Pityriasis Parkinsonism, Phricasmus Pantalgia, Anorexia.
Level III	Insomnia, Secondary Hypertension Tachypnea, Tachycardia Nausea, Hyperirritability
Level IV	Opisthotonus, Vomiting, Diarrhea, Gradual emaciation of the body's weight of 2Kg ~ 3Kg in a day, Spermotorrhea

In general, the adverse reaction is classified into 3 ranks as follows; Table 2

Table 2. Observation of the Adverse Reaction

Rank	Adverse Reaction
Level I	Xerostimia Inertia Dinics Drowsiness (more sleep than average hours) Hidrosis Neurasthenia
Level II	Constipation Palpitation Nausea
Level III	Photopsia Intoxicated Delirium Dyspnea Ashthenopia(diplopia, triplopia, etc.) Stranguria Vomiting

5. Keeping the Score

According to the rank, each symptom of level 0 is given 0 point, that of level I is 1 point, that of level II is 2 point, that of level III is 3 point, and that of level IV is 4 point. Irrespective of the serious or slight symptom s, the symptoms of rank are given a point. The scores of the withdrawal symptoms are added to those of the adverse reaction, and the total is compiled into statistics[11]. For 30 days the changes of weight had been observed.

Ⅵ. The Experimental Results

1. **The difference in the perfect controlling rate of withdrawal symptoms between the experimental group and the control group** is the following ; Table 3.

Table 3. Comparison of the Perfect Controlling Rate of Withdrawal Symptoms between the Experimental Group and the Contrast Group.

Time / Cases	24 hours(P)	48 hours(P)	72 hours(P)	5 days(P)	10 days(P)	Having withdrawal symptoms after 10 days
Experiment all group (56 cases)	14(25.0%)	14(25.0%)	19(33.9%)	49(87.5%)	53(94.6%)	3(5.4%)
Control group (49 cases)	2(4.1%)	2(4.1%)	3(6.1%)	12(24.5%)	29(59.2%)	20(40.8%)
Total (105 cases)	16(15.2%)	16(15.2%)	22(21.0%)	61(58.1%)	82(78.1%)	23(21.9%)
	u=2.98	u=2.98	u=3.49	u=6.53	u=4.39	u=4.48

There was a significant difference, $P<0.01$[12] between two groups. As the time went, the perfect controlling rate of the withdrawal symptoms in the experimental group got higher than that of the control group did. The one showed a much higher curative value than the other did. 5.4% of the experimental group showed the withdrawal symptoms observed after 10 days. On the other hand, 40.8% of the control group did.

2. The decrease in the withdrawal symptoms between the experimental group and the control group is as follows; Table 4 and Table 5.

Table 4. Progressive Decrease in Mean Value of Withdrawal Symptoms between the Experimental Group and the Control Group & Standard Deviation(SD)

Time / Cases	24 hours ±SD	48 hours±SD	72 hours±SD
Experimental group (56 cases)	16.55 ±5.98	3.66 ±3.33	3.95±4.88
Control group (49 cases)	10.02 ±8.64	2.82 ±2.66	2.82 ±2.44
Total (105 cases)	t=4.55 p<0.01	t=1.13 p>0.05	t=1.47 p>0.05

Table 5. Decrease in the Withdrawal Symptoms between the Experimental Group and the Control Group after 72 hours

Time / Cases	from 3 to 5 days	from 5 to 10 days	the number of the patients' recurrence after stopping taking medicine
Experimental group (56 cases)	31 (53.35%)	6 (10.71%)	2 (3.57%)
Control group (49 cases)	9 (18.37%)	20 (40.82%)	7 (18.92%) *12cases excluded because of sealed containment
Total (105 cases)	40 (38.10%) u=3.89 p<0.01	26 (40.82%) u=3.48 p<0.01	9 (8.57%) u=2.45 0.01<p<0.05

There was a significant difference, $p<0.01$ between two groups within 24 hours after taking medicine. The experimental group showed a drastic decrease in the withdrawal symptoms in comparison with the control group. From 48 hours to 72 hours after taking medicine, there was an insignificant difference, $p>0.05$ between two groups. Both groups did not show a striking decrease in the withdrawal symptoms. From 6 days to 10 days there was a significant difference, $p<0.01$ between two groups. The experimental group showed a drastic decrease in the withdrawal symptoms in comparison with the control group. By this fact we can see the effect of treating diseases for sure. After stopping taking medicine, there was a significant difference, $0.01<p<0.05$ in the patients' recurrence between two groups. The experimental group had a much lower relapse than the control group had.

3. The changes of weight is as follows; Table 6.

Table 6. Comparison of Mean Value of Gaining Weight between the Experimental Group and the Control Group & Standard Deviation

Mean Value & SD / Cases	Mean Value of Gaining Weight (Kg/ a day/ a person)	Standard Deviation
Experimental group (56 cases)	0.22	0.082
Control group (49 cases)	0.10	0.075
Total(105 cases)	t=7.78	$p<0.0005$

There was a significant difference, $p<0.0005$ between two groups. The experimental group gained more weight than the control group did.

4. The Decrease in the Scores of the Withdrawal Symptoms

The patients who were given marks not exceeding 13 points are as follows; Table 7.

Table 7. Decrease in Mean Value of Withdrawal Symptoms & Standard Deviation

Time / Cases	24 hours±SD	48 hours±SD	72 hours±SD	5 days±SD	10 days±SD
Experimental group(TYTJ prescribed for 14cases)	0	0	0	0	0
Control group (12 cases isolated)	12 ±5.68	9±8.32	6±3.93	3±2.49	0
Total (105 cases)	t=7.93	t=4.06	t=5.73	t=4.45	
			$p<0.0005$		

There was a significant difference, $p<0.0005$ between two groups. The experimental group showed more relieved withdrawal symptoms than the control group did. Besides, within 24 hours the one conspicuously showed the perfect controlling rate of the withdrawal symptoms in comparison with the other.

5. **After stopping taking medicine,** when the patients recovered the normal physiology, the number of the patients who had no relapse is showed in Table 8.

Table 8. Comparison of the Patients' Relapse after Stopping Taking Medicine

Cases \ Time	Stopping taking medicine within 3 days	Stopping taking medicine within 5 days	Stopping taking medicine within 10 days
Experimental group (56 cases)	18 (32.1%)	49 (87.5%)	53 (94.6%)
Control group (49 cases)	2 (6.1%)	12 (24.5%)	30 (61.2%)
Total	21 (20.0%)	61 (58.1%)	83 (79.0%)
	u=3.32 p<0.01	u=6.53 p<0.01	u=4.39 p<0.01

As the time went after stopping taking medicine, there was a significant difference, $p<0.01$ between two groups. The experimental group overcame the addiction and showed a much higher normal physiology than the control group did. The one had a much lower relapse than the other had after stopping taking medicine. By this fact, we can see that the experimental group has a higher curative value than the control group has.

6. The comparison of the adverse reaction is as follows ; Table 9 and Table 10.

Table 9. Mean Value of the Adverse Reaction and Standard Deviation

Time / Cases	24 hours ±SD	48 hours ±SD	72 hours ±SD	5 days ±SD	10 days ±SD
Experimental group (56 cases)	2.24±1.40	2.00±1.00	1.48±1.19	0	0
Control group (49 cases)	7.81±3.32	7.03±4.21	6.70±3.54	4.86±3.38	0.97±2.39
Total (105 cases)	t=3.96	t=8.67	t=10.39	t=10.78	t=3.03
			p<0.0005		

Table 10. Comparison of Mean Value of the Adverse Reaction between the group prescribed for only TYTJ and the one for Tramadol added to TYTJ

Time / Cases	24 hours ±SD	48 hours ±SD	72 hours ±SD	3 days ±SD	5 days ±SD
Tramadol added to TYTJ (29 cases)	2.24±1.40	2.00±1.00	1.48±1.19	0	0
only TYTJ (27 cases)	0	0	0	0	0
Total (56 cases)	t=8.39	t=10.39	t=6.46		
				p<0.0005	

There was a significant difference, $p<0.0005$ between two groups. When Tramadol added to TYTJ was prescribed for the patients, they showed a striking adverse reaction. When the patients took only TYTJ, they didn't show any adverse reaction. Therefore we can see that TYTJ do not cause any adverse reaction done by Tramadol.

Ⅵ. Discussion and Conclusion

1. TYTJ has the advantage of clearing the patients of toxic materials more adequately and positively than any other medicine has. The perfect controlling rate of withdrawal symptoms which the experimental group showed is 2.5% within 48 hours. The rate is 33.9% within 72 hours. It is 87.5% within 5 days. It is 94.6% on the tenth day. After 10 days it is only 5.4%.

2. TYTJ has so curative a power that it strengthens the patients' resistance to diseases and helps the patients to gain weight, because it invigorates their Qi(Primordial Energy) and removes toxic materials. The average increase in weight a day of the patients who belonged to the control group was only 0.10 Kg, but that of the patients who belonged to the experimental group was 0.22 Kg. There was a significant difference, $p<0.0005$ between two groups.

3. TYTJ has no both adverse reaction and drug dependence, which are indicated by Table 9 and Table 10. When the patients had symptoms such as pantalgia, insomnia, and diarrhea, Tramadol added to TYTJ was prescribed for the patients but their adverse reaction was slight. It was discovered that this slight adverse reaction is caused by Tramadol. On the other hand, the other medicines added to TYTJ caused serious adverse reaction.

4. 32.1% of the experimental group taking TYTJ had no relapse within 3 days in the case of recovering the normal physiology after stopping taking. 87.5% did not have within 5 days. 94.6% did not have within 10 days. In contrast, the contrast group showed the rate of recurrence, 6.1% within 3 days. It did 24.5% within 5 days. It did 61.2% within 10 days.

   The experimental group showed a significant difference, $p<0.001$. In

general, it took the experimental group 3 days to 8 days to recover the normal physiology. But it took the control group 8 days to 20 days to do so.

5. TYTJ cybernated the withdrawal symptoms, as indicated by Table 4 and Table 5, within 24 hours. Between 2 days and 3 days, both groups cybernated the withdrawal symptoms similarly. Between 6 days and 10 days, the experimental group strikingly cybernated the withdrawals symptoms.

6. The experimental group had a relapse of 3.57% after stopping taking TYTJ. The control group had 18.92%. The former showed a significant difference, $p < 0.05$.

7. It would be better for a bit of Tramadol or Diazepam which are added to TYTJ to be prescribed for the patients, when they have symptoms like pantalgia, insomnia, and diarrhea.

8. The experimental group taking TYTJ didn't have serious adverse reaction, drug dependence, drug habituation, drug idiosyncrasy, drug-induced diseases, drug addiction, and drug tolerence, which an antagonist therapy or a substitutional one has.

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