BILINGUAL PUBLISHING CO.
Pioneer of Global Academics Since 1984

Journal of Advances in Medicine Science
https://ojs.bilpublishing.com/index.php/jams

ARTICLE

Therapeutic Effect of Common Goldenrop Decoction Combined With Ramuli Cinnamomi Decoction in the Treatment of Patients with Insomnia during the Period of the Day from 11 PM to 3 AM

Na Duan* **Zhizhi Dong** **Xiyou Qi**

Beijing Huairou Hospital of Traditional Chinese Medicine, Beijing, 101400, China

ARTICLE INFO

Article history
Received: 6 January 2020
Revised: 13 January 2020
Accepted: 24 January 2020
Published Online: 31 January 2020

Keywords:
Common goldenrop decoction combined with ramuli cinnamomi decoction
Insomnia during the period of the day from 11 PM to 3 AM

ABSTRACT

Objective: To observe the clinical efficacy of common goldenrop decoction combined with ramuli cinnamomi decoction in the treatment of patients with insomnia during the period of the day from 11 PM to 3 AM. **Methods:** 80 patients with insomnia during the period of the day from 11 PM to 3 AM were randomly divided into control group and intervention group. The control group was treated with 1 mg of estazolam tablets at 9 PM every night; while the intervention group was given common goldenrop decoction combined with ramuli cinnamomi decoction based on the estazolam tablets. After 2 weeks of treatment and after 2 weeks of withdrawal, the improvement in sleep was observed. **Results:** After 2 weeks of treatment, the efficacy of the intervention group (97.5%) was significantly higher than that of the control group (75.0%). The difference was statistically significant. After 2 weeks of withdrawal, the intervention group still had an effective rate of 87.5%, which was significantly higher than that of the control group (55.0%). **Conclusion:** common goldenrop decoction combined with ramuli cinnamomi decoction can improve the short-term and long-term sleep quality of patients with insomnia during the period of the day from 11 PM to 3 AM.

1. Introduction

Sleeplessness, Traditional Chinese Medicine called "insomnia", patients in less severe cases fall asleep with difficulty, and even if fall asleep, they are easy to wake up, cannot fall asleep again after waking up, and sometimes fall asleep sometimes wake up; patients in severe cases cannot fall asleep all night. During the period of the day from 11 PM to 3 AM, the human body is in the charge of liver meridian and gallbladder meridian. It is found clinically that some patients are easy to wake up during the period of the day from 11 PM to 3 AM, and it is not easy for them to fall asleep again after waking up. In recent years, the author team draws on the experience of the predecessors, and actively summarizes the clinical experience, using common goldenrop decoction combined with ramuli cinnamomi decoction to treat this type of insomnia patients, found that there is a curative effect, summarized as follows:

**Corresponding Author:*
Na Duan,
Female,
Doctoral candidate, attending physician,
Department of encephalopathy, Beijing Huairou Hospital of Traditional Chinese Medicine, No.1 Houheng Street, Huairou District, Beijing, 101400, China;
E-mail:nana198528@163.com.

DOI: https://doi.org/10.30564/jams.v3i1.1616

2. Materials and Methods

2.1 General Information

80 outpatients and inpatients during the period from January 2017 to July 2018 in the department of encephalopathy in our hospital were selected. These patients meet the characteristics that when fall asleep, they are easy to wake up, cannot fall asleep again after waking up. Randomized digital table method was divided into control group and intervention group, 40 cases in each group, the course of disease was half a year to 5 years. The control group was 29-75 years old with an average of (42.21±2.23) years old; the intervention group was 29-74 years old with an average of (42.67±2.21) years old. There was no significant difference in the general age and duration of the two groups (P>0.05), which was comparable.

2.2 Case Selection Criteria

2.2.1 Diagnostic Criteria

Western medicine diagnosis refers to the diagnostic criteria for "sleeplessness" in the "Chinese Classification and Diagnostic Criteria for Mental Disorders".[1] The diagnosis of TCM (Traditional Chinese Medicine) refers to the diagnostic criteria and dialectical criteria of "insomnia" in the "Diagnostic and Efficacy Standards for TCM Syndrome" of the State Administration of TCM.[2]

2.2.2 Inclusion Criteria

In line with the above-mentioned Western and Chinese diagnostic criteria, The patients who are easy to wake up and cannot fall asleep again after waking up during the period of the day from 11 PM to 3 AM, aged 18-75, were chosen and the informed consents were signed.

2.2.3 Elimination Criteria

Exclude secondary sleeplessness caused by other physical illnesses or mental disorders; and exclude the use of anti-anxiety, depression, psychotropic drugs, such as lorazepam tablets, deanxit, serotonin reuptake inhibitors and other drugs.

2.3 Methods

2.3.1 Therapeutic Method

The patients in the control group were treated with estazolam tablets (Beijing Yimin Pharmaceutical Co., Ltd., State Food and Drug Administration Approval No.: H11020891), 1 mg each time, orally at 9 PM every night for 2 weeks. The intervention group was given common goldenrop decoction combined with ramuli cinnamomi decoction based on the estazolam tablets. The prescription is as follows: Bupleurum sinenses DC. 12g, Scutellaria baicalensis 10g, Codonopsis pilosula 10g, Pinellia ternate 9g, Licorice 9g, Ginger 6g, Jujubae 10g, Cassia twig 10g, Paeonia lactiflora pall 15g, one dose per day, decoction 2 times, morning and evening, also taken orally for 2 weeks.

2.3.2 Observation Method

The improvement in sleep was observed after 2 weeks of treatment and after 2 weeks of withdrawal.

2.4 Efficacy Judgment Criteria

Adopt the sleeplessness efficacy judgment criteria in "Guidelines for Clinical Research of New Drugs in Traditional Chinese".[3] Recovery: sleeplessness disappeared, able to sleep for more than 6h, with good sleep quality, good spirits after waking up; significant effect: sleeplessness improved, sleep time increased by more than 3h, and the depth of sleep increased; valid: sleeplessness has improved, sleep time increased by less than 3h; invalid: sleeplessness has no obvious improvement or even worse.

2.5 Statistical Processing

Use SPSS18.0 software statistics, t-test (metering data) and x^2 test (counting data) were performed separately, and P<0.05 was considered as significant difference.

3. Results

3.1 Comparison of Therapeutic Effects between the Two Groups

After 2 weeks of treatment, the effective rate of the control group was 75%, and the effective rate of the intervention group was 97.5%. The difference was statistically significant (P<0.05), as shown in Table 1 below.

Table 1. Comparison of efficacy between the two groups [n (%)]

Group	Total Number of Cases (n)	Recovery (n)	Significant Effect (n)	Valid (n)	Invalid (n)	Total Effective Rate [n (%)]
Control Group	40	4	16	10	10	30 (75.0)
Intervention Group	40	6	19	14	1	39 (97.5)

3.2 Comparison of Efficacy after 2 Weeks of Withdrawal

After 2 weeks of treatment, the control group discontin-

DOI: https://doi.org/10.30564/jams.v3i1.1616

ued estazolam tablets; the intervention group discontinued estazolam tablets and common goldenrop decoction combined with ramuli cinnamomi decoction. After 2 weeks of withdrawal, the effective rate of the control group decreased to 55%, and the effective rate of the intervention group was 87.5%. After 2 weeks of withdrawal, the effective rate of the intervention group was significantly higher than that of the control group, suggesting that the control group is more likely to relapse, see Table 2 below.

Table 2. Comparison of efficacy after 2 weeks of withdrawal [n (%)]

Group	Total Number of Cases (n)	Recovery (n)	Significant Effect (n)	Valid (n)	Invalid (n)	Total Effective Rate [n (%)]
Control Group	40	2	11	9	18	22 (55.0)
Intervention Group	40	5	18	12	5	35 (87.5)

4. Conclusion

The normal sleep of the human body depends on the "yin and yang in equilibrium", "Miraculous Pivot·Big Confusion Theory" believes that "Defensive Qi cannot enter the Yin, often stays in the Yang. Staying in the Yang, the Yang Qi is full and then the Yang Qiao meridian is vigorous; Defensive Qi cannot enter the Yin, and the Yin Qi is deficient, and then the eyes cannot close", "The pathogenesis of insomnia is that the Yang is not intersected with the Yin". The Defensive Yang is vigorous outside; while the Nutritive Yin is deficient inside, the Defensive Yang cannot enter the Yin, thereby cause insomnia. The normal sleep depends on the normal operation of the Defensive Qi and the Nutritive Qi. The ramuli cinnamomi decoction is a famous prescription for the reconciliation of Defensive Qi and the Nutritive Qi, and it is also called the "cinnamon twig decoction", which consists of five kinds of medicines: cassia twig, peony, radix glycyrrhizae preparata (honey-fried licorice root), ginger and jujube. In the prescription, the compatibility of liquorice and peony, jujube nourish the Yin with sour and sweet to assist the Nutritive Yin, which can better moisten and nourish the viscera, making the viscera in harmony and then the insomnia is eliminated,[4] based on these theoretical foundations, many experts conditioned insomnia based on ramuli cinnamomi decoction.[5]

During the period of the day from 11 PM to 3 AM, the human body is in the charge of liver meridian and gallbladder meridian. And fall asleep during this period, "the human lies on the bed, and then the blood goes back to the liver", when the blood goes back to the liver, the liver is nourished by blood, the so called "liver being the resolute viscera, when the human body is under the Yin, use the Yang to accomplish reconciliation", when the blood in the liver is enough, the liver Qi can be in normal free coursing, thereby the Qi and the blood accomplish unobstructed flow. The gallbladder is the "viscera with decisive character", and is also the viscera with pureness, is in charge of decision making, the gallbladder and the liver are mutual outside and inside, and if the gallbladder is not cleared, the liver will not be unobstructed, thereby cause the liver Qi and gallbladder Qi in an obstructed situation, and form stagnation leading to inflammation, the gallbladder inflammation with internal disturbance on state of mind which finally cause the insomnia, and even emotional restlessness, depression and other symptoms. In addition, the Shaoyang gallbladder meridian is the pivot, is in the charge of opening and closing, when the Shaoyang gallbladder meridian opening and closing are abnormal, the Yang is not intersected with the Yin, which can also cause the insomnia. Many studies and clinical work have found that, patients with insomnia during the period of the day from 11 PM to 3 AM In addition to poor sleep, patients often have emotional symptoms, such as upset, irritability, and even anxiety and depression, in addition to poor sleep,[6] which have laid the foundation for liver and gallbladder treatment of insomnia, in summarizing Ronglin Gao's insomnia treatment experience, Zonglian Liu[7] put forward insomnia treatment from the liver meridian and gallbladder meridian. Common goldenrop decoction comes from the medical sage Zhang Zhongjing's "Treatise on Febrile Diseases" and "Synopsis of Golden Chamber", involved in many of the provisions, which is a famous prescription for harmonizing Shaoyang gallbladder meridian, widely used in clinical application. In the prescription, radix bupleuri can play the role of solving pathogenic heat and dredging meridians and Qi. Scutellaria baicalensis clears the pathogenic heat and can clear and reduce the Yang inflammation. Pinellia ternate has the effect of harmonizing the stomach, calming the adverse-rising energy, and preventing or arresting vomiting. Codonopsis pilosula can regulate the Qi and blood, licorice and jujube have the effect of benefiting the Qi and stomach.[8] Common goldenrop decoction combined with ramuli cinnamomi decoction, the two can be used together to reconcile Shaoyang gallbladder meridian and accomplish the reconciliation of Defensive Qi and the Nutritive Qi, Not specializing in the treatment of insomnia and the symptom of sleeplessness is eliminated.

Due to various pressures such as work, life, and disease, many people are now prone to abnormal emotions such as anxiety and irritability, often resulting in insomnia due to poor venting, and it is not easy for some people to

DOI: https://doi.org/10.30564/jams.v3i1.1616

fall asleep again after waking up during the period of the day from 11 PM to 3 AM. This part of the patient is often accompanied by mental and psychological disorders such as anxiety and depression. In patients who wake up in the middle of the night and are not easy to fall asleep again, simple sedative drugs are often ineffective. After years of clinical exploration, the author team used the experience of predecessors to apply TCM classical prescription "common goldenrop decoction combined with ramuli cinnamomi decoction" in the treatment of patients with insomnia during the period of the day from 11 PM to 3 AM., and the clinical efficacy is more precise, based on which the study was developed. The results of the study showed that the clinical efficacy (97.5%) of the common goldenrop decoction combined with ramuli cinnamomi decoction group was significantly higher than that of the simple sedation group (75.0%), the difference was statistically significant, which suggests that the common goldenrop decoction combined with ramuli cinnamomi decoction does improve the sleeping status of patients with insomnia during the period of the day from 11 PM to 3 AM. Not only that, after 2 weeks of treatment, the sedative drug and common goldenrop decoction combined with ramuli cinnamomi decoction, after another 2 weeks of observation, it was found that the simple sedation group increased the inefficiency by at least 20% (75%-55%=20%), suggesting that it is easy to relapse after stopping the drug, the quality of sleep is easily deteriorated, and the drug dependence is high. The common goldenrop decoction combined with ramuli cinnamomi decoction group increased the inefficiency by about 10% (97.5%-87.5%) after 2 weeks of withdrawal, compared with 20%, the difference is more significant, suggesting that common goldenrop decoction can not only improve the patient's recent sleep, but also improve their long-term sleep, which may be less dependent on sedative drugs.

Due to limited geographical and time, the number of cases in this study is small and non-multi-center research is a deficiency. The author hopes to further expand the number of cases and geographical scope in the future, and conduct a more in-depth research on the patients whose incommnia during the period of the day from 11 PM to 3 AM, and inherit the classics of TCM.

In a broader sense, from the perspective of TCM health, we have been promoting a healthy lifestyle of "early to bed, early to rise", falling asleep during the period of the day from 11 PM to 3 AM make the blood goes back to the liver the liver Qi can be in normal free coursing, thereby the Qi and the blood accomplish unobstructed flow, but sleeping late (after 11 PM) has become the norm for many people, especially university and college students. Not falling asleep when one should go to bed, the Yang Qi doesn't enter the Yin when it supposed to do, thereby on the next day, the yang Qi will not raise, therefore, when one should be awake, he would be sleepy. Some scholars have studied that,[6] late sleep is one of the main culprits of the depression and aggravation of many people, and now many people's sub-health status has a certain relationship with this. Chinese medicine has the theory of "treating different diseases with the same method", for many patients with emotional disorders derived from the insomnia during the period of the day from 11 PM to 3 AM, the author found that common goldenrop decoction combined with ramuli cinnamomi decoction also has a certain effect in the clinical application, looking forward to doing more research on this area.

References

[1] Chinese Medical Association Psychiatric Branch. Classification and Diagnostic Criteria for Mental Disorders in China (Third Edition)[S]. Jinan: Shandong Science and Technology Press, 2001:118-119. (in Chinese)

[2] State Administration of Traditional Chinese Medicine. TCM Syndrome Diagnosis and Treatment Standards[S]. Nanjing: Nanjing University Press, 1994:19-20. (in Chinese)

[3] Xiaoyu Zheng. Guiding Principles for Clinical Research of New Drugs in Traditional Chinese Medicine[S]. Beijing: China Medical Science and Technology Press, 2002:88. (in Chinese)

[4] Jun Zuo et al. Medical Case Analysis of Ramuli Cinnamomi Decoction in the Treatment of the Insomnia without the Reconciliation of Defensive Qi and the Nutritive Qi[J]. Chinese Medicine Information, 2016, 33(5):32-33. (in Chinese)

[5] Fengzhe Su, Jie Lu, Ximing Liu, et al. Professor Zhizheng Lu's clinical experience in treating insomnia[J]. Word Journal of Integrated Traditional and Western Medicine, 2009, 4(5):312-314. (in Chinese)

[6] Li Chun, Xiaoyuan Liang, et al. Investigation of the relationship between sleeplessness during the period of the day from 11 PM to 3 AM and depression[J] Asia-Pacific Traditional Medicine, 2016, 12(23):113-115. (in Chinese)

[7] Zonglian Liu, Zutao Gao, Ping Li. Director Ronglin Gao's experience in treating sleeplessness from the theory of liver and gallbladder[J]. World Journal of Sleep Medicine, 2014, 6(1):368-370. (in Chinese)

[8] Xihong Yan. Common goldenrop decoction combined with ramuli cinnamomi decoction in the use of menopausal syndrome patients[J]. Journal of Clinical Medicine Literature, 2018, 5(38):139. (in Chinese)

 DOI: https://doi.org/10.30564/jams.v3i1.1616