Advances in Clinical Application and Pharmacological Research of Mongolian Medicine Sugemule-3 and Related Formulas

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Abstract This paper reviews the related formulas of Sugemule, introduces the advances in research of clinical application of these formulas in treating Heyi type insomnia, cardiac diseases, and renal diseases. Besides, it summarizes pharmacological research advances regarding these formulas, including their anti-insomnia effects, cardioprotective properties, and ovarian function preservation capabilities. This study is expected to provide a reference and insight for in-depth and systematic research on classical Mongolian medicinal formulas.

Key words Sugemule-3 Decoction, Related formulas, Clinical application, Pharmacology, Review

1 Introduction

Mongolian medicine Sugemule-3, first recorded in *Follow-up Edition of The Four Medical Tantras*, is composed of Fructus Amomi Rotundus, Herba Apii Graveolentis and Fructus Piperis Longi, and is mainly used to treat Heyi type insomnia (Heyi is a characteristic syndrome in Mongolian medicine). Sugemule-4, composed of Fructus Amomi Rotundus, Herba Apii Graveolentis, Fructus Piperis Longi, and Semen Ziziphi Spinosae, recorded in the improved traditional formula of Professor Chaganfu in Mongolian medicine, and is mainly used to treat insomnia caused by excessive Heyi. Sugemule-3 Decoction has definite curative effect and wide clinical application, but its drug composition is complex and difficult to study. The study of its prescription rules and scientific connotation is helpful for its further research, development and utilization.

In this study, we summarized and analyzed the clinical and pharmacological studies of Sugemule-3 Decoction and its main related formulas, providing a new perspective from the perspective of related formulas, and providing research inspiration for further study of Sugemule-3 Decoction.

2 Related formulas of Sugemule-3 Decoction

Related formulas of Sugemule-3 Decoction are listed in Table 1.

3 Clinical application of relative formulas

3.1 Treatment of Heyi type insomnia In Mongolian medical theory, the Heyi type insomnia has its unique etiology and pathogenesis. Mongolian medicine believes that insomnia symptoms can be improved by regulating the balance of Heyi, Xila and Badagan. For example, some patients suffer from excessive Heyi due to long-term mental stress, such as difficulty in falling asleep, dreaminess and easy awakening. In a study, Sarentuya[1] selected 96 patients with insomnia to use Sugemule-3 Decoction for treatment, and the results showed that the total effective rate was 96.9%, with high safety and few adverse reactions. Sugemule-3 Decoction can improve sleep quality by regulating nervous system function, alleviating anxiety, depression and other emotions. In another study, the clinical efficacy of Sugemule-3 Decoction combined with warm needling therapy of Mongolian medicine in the treatment of insomnia[2] was significantly better than that of conventional Anshen Bunao Liquid. Yuandan *et al.*[3] collected patients with Heyi type insomnia and used Sugemule-3 Decoction combined with Mongolian moxibustion and acupuncture therapy[4]. Through clinical observation, it was found that Sugemule-3 Decoction could significantly improve the clinical signs and symptoms and signs of patients with Heyi type insomnia, improve sleep quality, improve sleep efficiency and reduce the number of Pittsburgh sleep quality index. In Mongolian medicine, it is better to use milk decoction to inhibit Heyi type insomnia. Deng Siqin[5] studied 60 patients with insomnia in two groups. They were treated with Sugemule-3 Decoction decocted with water and pure milk respectively. The total effective rate of the pure milk decoction group was 93.3%, and the total effective rate of the water decoction group was 83.3%. This conclusion proved that Sugemule-3 Decoction decocted with milk is more effective in the treatment of insomnia.

3.2 Treatment of myocardial disease Sugemule-related formulas have also shown efficacy in cardiovascular disease. Modern studies have shown that this formula may regulate the cardiovascular system in many ways. For some patients with palpitation and chest distress, Sugemule formula can regulate the circulation of qi and blood in the heart and improve myocardial blood supply. From the perspective of Mongolian medicine, it can adjust the body's qi and blood veins, so that cardiovascular function can be restored to

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Table 1 Related formulas of Sugemule-3

Formula	Composition	Indications	Source
Sugemule-3	Fructus Amomi Rotundus, Herba Apii Graveolentis, Fructus Piperis Longi	Heyi disease, insomnia	*Follow-up Edition of The Four Medical Tantras*
Sugemule-4	Fructus Amomi Rotundus, Herba Apii Graveolentis, Fructus Piperis Longi, Semen Ziziphi Spinosae	Insomnia caused by excessive Heyi	Improved traditional formula of Professor Chaganfu in Mongolian medicine
Sugemule-7	Fructus Amomi Rotundus, Radix Asparagi, Rhizoma Gymnadeniae, Lignum Aquilariae Resinatum, Semen Myristicae, Rhizoma Polygonati, and Flos Caryophylli	Inhibiting Heyi, strengthening body constitution, regulating and nourishing blood, warming uterus and stop leucorrhea, and mainly used for treating heart and kidney Heyi diseases, excessive leucorrhea, lumbago due to stagnation of qi, soreness of waist and legs, cold lower abdomen, irregular menstruation, heaviness and weakness.	*Guan Zhe Zhi Zi* (a work on clinical prescriptions of Mongolian medicine)
Sugemule-10	Fructus Alpiniae Oxyphyllae, Rhizoma Zingiberis, Fructus Piperis Longi, Semen Nelumbinis, Semen Torreyae, Moschus, Sal Ammoniacus, Fructus Abutili, and Caesalpinia minax Hance	Dispelling kidney cold and promoting urination, used for treating kidney cold, lumbago, anuria, kidney, bladder stones and other diseases, a main prescription for the treatment of kidney cold.	*The Four Medical Tantras*

normal. For example, in some clinical observations, some patients with coronary heart disease and palpitation symptoms, after taking Sugemule related formulas, the frequency of palpitation attacks decreased, and the electrocardiogram also improved to a certain extent. For example, Sarengaowa[6] collected 60 patients with arrhythmia and insomnia, indicating that the number of premature beats in the Sugemule-3 Deoction group was less than that in the metoprolol tartrate positive control group, and the heart rate variability index was higher than that in the metoprolol tartrate tablet group, suggesting that Sugemule-3 Deoction can improve heart rate variability and cardiac autonomic nervous function, and play an anti-arrhythmic role. Li Chen[7] collected 70 patients with diastolic heart failure, indicating that the left ventricular isovolumic relaxation time in the Mongolian medicine Sugemule-3 Deoction group was significantly shorter than that in the western medicine group, and the sleep quality and quality of life were significantly improved. Bai Chunming[8] collected patients with acute myocardial infarction from 2012 to 2016 and treated them with Sugemule-3 Deoction. The results showed that the total effective rate of patients in the treatment group after treatment was significantly lower than that in the reference group ($P<0.05$); the peak concentrations of troponin and creatine kinase isoenzyme in the treatment group after treatment; the results showed that Sugemule-3 Deoction was effective in the treatment of patients with acute myocardial infarction and could effectively protect the myocardial injury of patients.

3.3 Treatment of kidney disease According to Mongolian medicine, kidney stones fall under the category of "renal stone stagnation". The condition arises from an imbalance of the three roots (Heyi, Xila, and Badagan) and seven essences (essence, flour, meat, fat, bone, marrow and essence of food), which leads to increased accumulation of pathogenic blood and yellow fluid during the separation of nutrients from waste products. These pathological substances stagnate in the renal channels, causing renal dysfunction. When the accumulated pathogenic blood and yellow fluid are further condensed by the heat of urine, they exacerbate renal contraction. Clinical studies demonstrate that patients may present with microscopic or gross hematuria, renal colic, hydronephrosis, concurrent infections, renal parenchymal damage, and impaired renal function. Severe cases can progress to uremia and death. Clinical observations of kidney stone patients treated with Sugemule-10 for 21 d showed significant therapeutic effects[9-10].

4 Pharmacological research of Sugemule related formulas

4.1 Anti-insomnia effect The aqueous extract of Sugemule-3 Deoction[11] has good sedative and hypnotic effects, and its mechanism may be related to the levels of central neurotransmitters 5-HT, GABA and cytokine IL-1β in insomnia rats. Mongolian medicine warm needling combined with Sugemule-3 Deoction[12] can improve the pathological changes of neurons in cerebral cortex, hypothalamus and hippocampus of insomnia model rats, and may improve sleep through the content of IL-1β, IL-2, IL-6 and TNF-αin serum of insomnia rats and the content of GABA in 5-HT hypothalamus. The study of Guo Jialin et al showed[13] that the mice of Cancer Research Institute of Philadelphia (ICR) were used to establish the insomnia model, and then the sleep incubation period time, sleep time and sleep rate of the mice were observed. The results showed that the sleep rate, sleep time and sleep incubation period of the Anshen Bunao Liquid control group and Sugemule-4 administration group were better than those of the normal control group, and the differences were statistically significant ($P<0.05$). The results showed that Sugemule-4 decoction had sedative and hypnotic effects. The mechanism may be related to the decrease of the contents of DA and GLU in the brain of mice, which can improve the insomnia of mice. Yang Rui used[14] non-targeted metabonomics method to analyze the sleep state of chronic stress rats with Sugemule-4, indicating that Sugemule-4 played an anti-insomnia role by affecting the amino acid metabolic pathways of tryptophan, histidine and tyrosine and intestinal flora metabolism. The study of Du Lina *et al.*[15] showed that Sugemule-4 Decoction improved the changes of related neurotransmitters, brain-gut peptide content and intestinal flora in insomnia model rats.

4.2 Myocardial protection Wang Yu *et al.*[16] found that Sugemule-3 Deoction had a protective effect on myocardial hypertrophy induced by isoproterenol in rats, and its mechanism was that Sugemule-3 Deoction reduced the activity of Caspase-3/9 induced by isoproterenol and down-regulated the expression of Caspase-3/9, thereby alleviating the conversion of myocardial hypertrophy to heart failure. Guo Xin *et al.*[17] found that Sugemule-3 Deoction could effectively improve rat cardiomyocyte hypertrophy, and its mechanism may be to regulate oxidative stress and endoplasmic reticulum stress through the expression of Calumenin protein, thus affecting the occurrence of apoptosis. It was further found that the therapeutic effect on isoproterenol (ISO)-induced injury of mouse cardiomyocytes may be related to the regulation of SERCA2a protein[18]. Another study has shown[19] that Sugemule-3 Deoction can improve the cardiac function of rats with heart failure by regulating the expression of mitochondrial fusion/fission related proteins and mitochondrial apoptosis related proteins. Hu Pengfei *et al.*[20] found that Sugemule-3 Deoction could intervene in the arrhythmia of mice with immune dilated cardiomyopathy (IDCM), and its mechanism may be achieved by increasing the expression of gap junction proteins CX40 and CX43.

4.3 Ovarian protection In Mongolian medicine, ovarian premature failure and physiological decline of ovarian function are categorized under the syndrome of "excessive Heyi" or "predominant Badagan". Studies by Chunlian *et al.*[21] demonstrate that Sugemule-7 can delay ovarian aging and improve ovarian function by regulating protein expressions across multiple pathways, including the nicotinate-nicotinamide metabolism pathway, pancreatic secretion pathway, salivary secretion pathway, innate immune system regulation pathway, immune system pathway, and complement cascade regulation pathway. Further research[22-23] reveals that Sugemule-7 protects ovarian endocrine and reproductive functions through multiple mechanisms: Inhibiting elevated levels of TNF-α, IL-6, and CFH; upregulating TGF-β1 and SOD expression while downregulating TSP-1; Improving ovarian microcirculation; preventing ovarian fibrosis; creating a favorable microenvironment for follicular development; promoting splenic lymphocyte proliferation; enhancing immunity. These multifaceted actions collectively exert protective effects on both endocrine and reproductive functions in chemotherapy-induced ovarian hypofunction rat models, effectively preserving ovarian function in rats with ovarian insufficiency.

5 Discussion

Comparing Mongolian medicine Sugemule-3 and Sugemule-4 and their related prescriptions, we can see that each formula mainly contains Fructus Amomi Rotundus, Herba Apii graveolentis and Fructus Piperis Longi, and mainly contains Semen Ziziphi Spinosae. Root prescriptions and similar formulas commonly used in Mongolian medicine are mainly used to treat Heyi disease to improve insomnia, and related formulas are also used for myocardial diseases and kidney diseases. Modern pharmacological studies have focused on anti-insomnia, myocardial protection and ovarian function, showing its good application value.

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