

Research Progress on the Use of Yue ju Pill in the Treatment of Functional Dyspepsia

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Abstract: *Yueju Pill are derived from *Danxi Xinfu*; the formula comprises Atractylodes lancea, Cyperus rotundus, Ligusticum chuanxiong, Shenqu and Gardenia jasminoides, and is primarily indicated for relieving various forms of stagnation. Later generations of medical practitioners have also extended its use to treat disorders of the digestive and nervous systems, amongst others. This article provides a systematic review of the progress made in clinical and basic research on Yueju pill in the treatment of functional dyspepsia. Clinical studies have shown that Yueju pill can effectively alleviate the symptoms of functional dyspepsia whilst causing few adverse reactions; their mechanism of action is primarily related to the regulation of the gut microbiota and the brain-gut axis.*

Keywords: Functional dyspepsia, Yueju pill, Traditional Chinese medicine.

1. Introduction

Functional dyspepsia (FD) is a common functional gastrointestinal disorder. According to the Rome IV criteria, FD is defined as a condition characterised by one or more of the following symptoms: postprandial fullness, early satiety, upper abdominal pain, or a burning sensation in the upper abdomen, where the symptoms cannot be explained by organic, systemic or metabolic diseases [1]. FD has a high prevalence worldwide and significantly impacts patients' quality of life. A key mechanism underlying the onset and progression of FD is abnormal gut-brain interaction caused by multiple factors [2], with diet and infection being the primary precipitating factors. Currently, Western medical treatment focuses primarily on symptomatic relief and addressing the underlying causes, including prokinetic agents, acid-suppressing drugs and antidepressants. Although these treatments demonstrate some efficacy, the recurrence rate remains high; traditional Chinese medicine (TCM) offers unique advantages in the treatment of this condition.

The YueJu Pill originates from *Danxi Xinfu* [3]; the formula comprises Atractylodes lancea, Cyperus rotundus, Ligusticum chuanxiong, Shenqu and Gardenia jasminoides, and is primarily used to relieve various forms of stagnation. Adapted by later generations of physicians, it can be applied to treat digestive system disorders such as functional dyspepsia and peptic ulcers. In Traditional Chinese Medicine, functional dyspepsia (FD) can be categorised under conditions such as 'gastric fullness', 'epigastric pain' and 'epigastric discomfort'. Its pathogenesis involves impaired Qi circulation in the middle jiao and a failure of the spleen and stomach to perform their ascending and descending functions; this aligns closely with the therapeutic effects of Yueju pill, which are to 'regulate Qi and resolve stagnation, soothe the epigastrium and relieve fullness'. In recent years, there has been a growing body of clinical and basic research on the treatment of FD with Yueju pill. This article aims to provide a systematic review of the research progress, with a view to offering guidance for its clinical application and future research.

2. Origins of the Formulation

Yueju Pill are derived from the *Danxi Xinfu*, also known as Chuanxiong-Shu pill. The formula consists of Atractylodes lancea, Cyperus rotundus, Ligusticum chuanxiong, Shenqu and Gardenia jasminoides, and is primarily used to resolve various forms of stagnation. Zhu Danxi held that 'when qi and blood are in harmony, no illness arises; but once stagnation occurs, various diseases follow. Therefore, most illnesses in the human body arise from stagnation.' Although 'all illnesses arise from stagnation'—which manifests as Qi stagnation, dampness stagnation, phlegm stagnation, fire stagnation, blood stagnation and food stagnation—these six forms of stagnation are interrelated, yet Qi stagnation lies at the core, with pathological changes primarily occurring in the middle jiao, specifically the spleen and stomach. The Yueju Pill is specifically formulated to address these six forms of stagnation; within the formula, Xiangfu promotes the flow of Qi and resolves stagnation to treat Qi stagnation, Chuanxiong (Ligusticum) promotes blood circulation and resolves stasis to treat blood stagnation; Cangzhu (Atractylodes) dries dampness and regulates the spleen to treat dampness stagnation; Shenqu (Malt) aids digestion and relieves food stagnation; and Zhizi (Gardenia) clears heat and purges fire to treat fire stagnation. When these five herbs are used in combination, they regulate the flow of qi in the middle jiao; once qi flows smoothly, all forms of stagnation are naturally resolved. Later-generation medical authorities also expanded its application to other conditions; for instance, *Zhengzhi Zhunsheng* [4], which states that it treats epigastric fullness, epigastric pain and toothache attributable to stagnation. Modern research has also demonstrated that Yueju pill can be used for digestive system disorders such as functional dyspepsia, gastro-oesophageal reflux disease, peptic ulcers and atrophic gastritis [5].

3. Functional Dyspepsia

based on its clinical manifestations, can be categorised under the Traditional Chinese Medicine (TCM) terms 'gastric fullness', 'epigastric pain' and 'epigastric rumbling' in

Traditional Chinese Medicine. The primary site of the disease is the stomach, though it is associated with the liver and spleen. The pathogenesis involves impaired qi circulation in the middle jiao and a failure of the spleen and stomach to perform their ascending and descending functions. Differential diagnosis and classification primarily comprise five common patterns: spleen deficiency with qi stagnation, liver-stomach disharmony, spleen-stomach damp-heat, spleen-stomach deficiency-cold (weakness), and a pattern of mixed cold and heat [1]. Among these, the core of the Liver-Stomach Disharmony pattern lies in the stagnation of Liver Qi, which rebels and invades the Stomach, causing the Stomach to lose its harmonious descent; episodes are often triggered or exacerbated by emotional distress. This pattern is the primary therapeutic indication for Yueju Pill in modern research.

4. Clinical Applications

4.1 Yueju Pill and Their Modified Formulations for the Treatment of FD

The formula for Yueju Pill is concise and has had a profound influence on subsequent approaches to treating 'depression' - related disorders. Although Yueju Pill were not specifically designed to treat FD, the core pathogenesis of FD of the liver-stomach disharmony type lies in the stagnation of liver qi, which then invades the stomach; which aligns with the Yueju Pill's therapeutic philosophy of treating the 'Six Stagnations' with a focus on qi stagnation. Clinical trials have also demonstrated its good efficacy in treating FD; however, in clinical practice, the Yueju Pill is rarely used alone to treat the condition, and is often modified according to clinical symptoms or combined with other formulas for treatment. Wang Xuewen [6] divided 70 patients with FD into a control group treated with Wai Tai Fu Ling Decoction and a treatment group to which Yue Ju pill were added to the control group's regimen; The results showed that the overall response rates for the treatment group and the control group were 91.40 per cent and 71.40 per cent respectively; it was concluded that the combined treatment of Wai Tai Fu Ling Decoction and Yue Ju Pill was more effective than Wai Tai Fu Ling Decoction alone. Yang Zhaoru [7], through a randomised controlled clinical trial, found that Jiawei Yueju Decoction effectively improved the clinical symptoms of postprandial discomfort syndrome of the 'liver-stomach disharmony' type, alleviated anxiety and depression, improved sleep quality, enhanced quality of life, reduced the recurrence rate, and demonstrated high safety, thus possessing good clinical development potential. Liu Jun [8], through a comparative study of Yueju Formula and Qi-Stagnation Gastric Pain Granules, found that Yueju Formula was more effective in treating functional dyspepsia of the liver-stomach disharmony type. Cheng Huanxing [9] and colleagues randomly divided 86 patients into a control group and an observation group, each comprising 43 patients. The control group was treated with a combination of flupenthixol and melitracen tablets and domperidone tablets, whilst the observation group was treated with a modified combination of Zhishu pill and Yueju Pill. The treatment with the modified combination of Zhishu pill and Yueju Pill proved to be more effective for functional dyspepsia of the 'liver-stagnation and qi-stagnation' type, improving clinical

symptoms and reducing the recurrence rate.

4.2 Treatment of FD with Yueju Pill in Combination with Other Therapies:

Yueju Pill may also be combined with external TCM therapies such as acupuncture and acupoint thread implantation, and may be used in conjunction with psychological interventions to address the emotional factors associated with functional dyspepsia. Shan Chongwu [10] compared the treatment of FD with acupuncture combined with Yueju Pill against conventional Western medication and found that the combination of acupuncture and Yueju pill effectively alleviated clinical symptoms in patients with functional dyspepsia and improved their anxiety and depression. Zhao Wenlin [11] et al. conducted a randomised controlled clinical trial comparing acupoint thread implantation alone with acupoint thread implantation combined with Yueju Baohe pill; they found that the combination of Yueju Baohe Pill and acupoint thread implantation effectively improved serum gastrointestinal hormone and pepsinogen levels in patients with FD of the 'liver-stomach disharmony' type, promoted gastric motility, and consequently improved gastrointestinal function. Wang Ping [12] et al. treated patients with FD accompanied by anxiety and depression using the Ziwu Liuzhu acupoint-opening therapy in combination with Yueju pill; this effectively improved patients' anxiety and depression as well as their clinical symptoms, increased serum gastrin and pepsinogen levels, and significantly enhanced clinical efficacy. Lin Hong [13] treated 72 patients with functional dyspepsia of the 'liver-stomach disharmony' type using the Jiawei Yueju Formula combined with psychological intervention, achieving an overall response rate of 97.06 per cent. The study concluded that the combination of the Jiawei Yueju Formula and psychological intervention yields good clinical therapeutic results for functional dyspepsia of the 'liver-stomach disharmony' type.

4.3 Treatment of FD with Yueju Pill in Combination with Western Medicine

Some researchers have compared the efficacy of treating FD with Yueju Pill in combination with modern Western medicine against that of Western medicine alone, and found that the addition of Yueju Pill yields better therapeutic outcomes for FD, whilst resulting in fewer adverse reactions. Yang Su [14] found that the modified Yueju pill combined with flupenthixol and melitracen tablets were more effective in treating FD accompanied by anxiety and depression (liver-stomach disharmony syndrome) than the standard combination of Western medicines with anti-anxiety and antidepressant drugs; furthermore, they resulted in fewer adverse reactions and better long-term efficacy. This approach is clinically applicable for the treatment of functional dyspepsia accompanied by anxiety, depression and liver-stomach disharmony syndrome, and warrants further research. Dai Yehong [15] et al. found that, when Buqi Yunshen Decoction combined with Yueju pill was administered to patients with FD in addition to standard Western medication, the overall clinical response rate was

higher than that achieved with standard Western medication alone.

4.4 Experiences and Theoretical Discussions by Leading Experts on the Treatment of FD with Yueju pill

A number of medical practitioners have discussed their clinical experiences with the use of Yueju Pill in the treatment of FD. Yin Qiang [16] and colleagues, whilst working alongside Professor Gan Chuan, summarised his approach of frequently using Yueju Pill as a basis for flexible modification in the treatment of patients with functional dyspepsia of the 'liver-stomach disharmony' type, noting that the clinical efficacy was well-established. Jin Tianyi [17] and colleagues maintain that the Yueju method guides the treatment of functional dyspepsia by 'restoring the qi mechanisms of the liver and spleen, whilst emphasising qi stagnation and phlegm stagnation'. Professor Zhang Tiezhong [18] approaches the treatment of this condition from the perspective of the 'Six Stagnations', positing that liver qi stagnation is the initiating mechanism; at the onset of the disease, the primary focus is on 'qi', which gradually evolves from qi stagnation into stagnations of blood, fire, phlegm, dampness and food. Treatment should be guided by the general principle of 'promoting the flow of qi and resolving stagnation'. Professor Zhang frequently combines Yueju pill with Lily and Wuyao Decoction, achieving significant therapeutic results. Professor Feng Wujin [19] often approaches the treatment of functional dyspepsia from the patient's psychological perspective; guided by the theory of 'treating from the perspective of the liver', he flexibly modifies the formula based on Yueju pill.

In summary, Yueju pill has demonstrated significant efficacy in the clinical treatment of FD, with few adverse reactions and a low recurrence rate. They are particularly effective for FD accompanied by emotional symptoms, and their long-term efficacy is superior to that of treatment with Western medicine alone.

5. Experimental Study

The pathogenesis of FD involves a variety of factors, such as alterations in gastrointestinal motility, impaired barrier function, changes in the gut-brain axis, inflammation and psychological factors [20]. Experimental studies have shown that Yueju pill have a beneficial therapeutic effect on FD, primarily by promoting gastrointestinal motility. Their mechanism of action may be related to the regulation of the gut microbiota and the brain-gut axis; in recent years, network pharmacology studies have also investigated the signalling pathways and targets involved in the treatment of FD with Yueju pill.

5.1 Regulating the Brain-gut Axis

A key mechanism regulating the onset and progression of functional dyspepsia (FD) via the brain-gut axis is the abnormal gut-brain interaction caused by various factors; research has shown that brain-gut peptides play a significant role in the pathogenesis of functional dyspepsia [21]. Studies have confirmed that Yueju pill can significantly increase the levels of excitatory brain-gut peptides—such as serum motilin (MTL), substance P (SP), somatostatin (SS),

5-hydroxytryptamine (5-HT) and tryptophan hydroxylase (TPH), whilst simultaneously reducing the levels of inhibitory neuropeptides such as vasoactive intestinal peptide (VIP) and nitric oxide (NO). Gu Ying [22] and colleagues, through experiments on 60 rats, found that Yueju pill have a beneficial therapeutic effect on FD; the mechanism may be related to the regulation of gut microbiota structure and the secretion of neuropeptides, as well as the restoration of brain-gut axis function. Shen Haoran [23] and colleagues concluded from rat experiments that the role of Yueju pill in the prevention and treatment of FD may be related to the regulation of the 5-HT signalling pathway, increased secretion of TPH, promotion of neuropeptide secretion, and enhancement of gastric motility. Ye Ying's [24] experimental study indicated that the mechanism by which Yueju pill increase gastrointestinal motility in rats with FD may involve influencing gastrointestinal function by increasing 5-HT expression in gastric antral tissue and downregulating serum VIP levels. Wang Yan et al. [25], using a mouse model of comorbid depression and functional dyspepsia induced by chronic unpredictable mild stress, concluded that Yueju pill may exert their effects by activating the hippocampal-pituitary adenylate cyclase-activating peptide (PACAP)/ pituitary adenylyl cyclase-activating peptide type I receptor (PAC1-R) to reduce inflammatory factors, elevate levels of brain-derived neurotrophic factor (BDNF), and improve depression-like behaviour and functional dyspepsia in mice. Yu Zehe [26] found that Yueju pill has a good preventive and therapeutic effect on functional dyspepsia (FD); the mechanism may be related to regulating the structure of the gut microbiota, increasing the expression levels of genes and proteins associated with the gut-brain axis, and enhancing gastrointestinal motility. Animal studies by Xu Jiagan [27] et al. indicated that the mechanism by which Yueju pill accelerate gastrointestinal motility in rats may be related to the upregulation of MTL levels and the downregulation of NO levels. Liu Fen [28] and colleagues found through experimental research that *Atractylodes lancea* extract can increase the levels of MTL, SP and SS in rat plasma, as well as the expression levels of Toll-like receptor 4 (TLR4) in duodenal, jejunal and ileal tissues, thereby improving gastrointestinal motility and immune function in rats with experimental spleen deficiency.

5.2 Modulation of the Gut Microbiota

A meta-analysis [29] suggests that interventions targeting the microbiota can alleviate FD symptoms by altering the structure and function of the gut microbiota. Studies have indicated that the gut microbiota may improve the clinical symptoms of FD by enhancing intestinal barrier function, reducing visceral hypersensitivity and regulating gastrointestinal motility [30], whilst Yueju pill and their individual herbal constituents may play a role in modulating the structure of the gut microbiota. Through animal experiments, Liu Ping et al. concluded [31] that in the Chuanxiong polysaccharide intervention group, the gut microbiota structure of mice underwent significant changes: the relative abundance of certain beneficial bacteria was significantly restored, and the diversity of the gut microbiota was effectively enhanced. These changes in the gut microbiota were closely associated with improvements in the mice's immune function.

The regulation of the above mechanisms does not occur in isolation, but rather through dynamic interactions via neural, hormonal and immune pathways. Modern [32][33] network pharmacology also predicts that the targets, biological processes and pathways involved in the treatment of functional dyspepsia with Yueju pill encompass a variety of tissues and organs, including the stomach, liver, gallbladder, pancreas and blood vessels.

6. Conclusion

In summary, the mechanism by which Yueju pill treat FD involves multiple levels, including the regulation of the brain-gut axis and the gut microbiota, reflecting its multi-target, holistic regulatory characteristics. Clinical studies have also confirmed its significant efficacy, both when used alone and in combination with other treatments, whilst demonstrating a high safety profile. However, existing research has largely focused on theoretical studies and small-scale clinical trials, with a lack of large-scale, multicentre randomised controlled trials. Future research could further focus on: conducting large-scale, multicentre randomised controlled trials; thoroughly investigating the interactions between its active constituents and key targets; and developing modern dosage forms that are more convenient to take.

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