



Patents research and development prospects of spleen-invigorating health food with the homology of medicine and food from 2000 to 2022: a bibliometric analysis

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ABSTRACT

Objective To analyze the current status and development trends of the patents of spleen-invigorating health food with the homology of medicine and food in China, and to provide ideas and references for the research and development of traditional Chinese medicine (TCM) spleen-invigorating health food with the homology of medicine and food.

Methods The State Administration for Market Regulation website's "Special Food Information Query Platform" and the incoPat global patent database were searched in this study. Based on the methods of bibliometrics, the registered health food and patents related to spleen-invigorating health food with the homology of medicine and food in China were sorted out. Furthermore, the research and development numbers, provinces, institutions, technology and efficacy classification, major drugs, active ingredients and others of invigorating spleen health food in China were analyzed, and filtered patent data were visualized and analyzed by R programming language and Cytoscape software.

Results A total of 285 patents of health food with the homology of medicine and food for invigorating spleen were included and analyzed. From 2012, the patent registration numbers of these spleen-invigorating health food with the homology of medicine and food increased significantly in China. Over the past 20 years, the top five provinces in terms of patent disclosures were Guangdong, Anhui, Jiangsu, Shandong, and Guangxi. It was found that the technical efficacy of over 20 patents was described as "immune enhancement" "digestion" "disease prevention", etc. Patent applications were mainly aimed at the research and development of the preservation of food or ingredients, the specific therapeutic activity of compounds, and pharmaceutical preparations, which were led by corporation research and development registrations, and supplemented by applications from research institutions and individuals. Among the 285 patents, the top 10 raw materials of spleen-invigorating health food with the homology of medicine and food were Shanyao (*Dioscoreae Rhizoma*), Fuling (*Poria*),

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Shanzha (*Crataegi Fructus*), Baizhu (*Atractylodis Macrocephalae Rhizoma*), Chenpi (*Citri Reticulatae Pericarpium*), Dazao (*Jujubae Fructus*), Gancao (*Glycyrrhizae Radix et Rhizoma*), Fengmi (Mel), Maiya (*Hordei Fructus Germinatus*), and Dangshen (*Salviae Miltiorrhizae Radix et Rhizoma*). The main functions were to nourish spleen and replenish Qi, invigorate spleen and benefit lungs, nourish blood and promote fluid production, and nourish spleen and stomach.

Conclusion The main drug composition and functional components of spleen-invigorating health food with the homology of medicine and food are relatively clear, and the technical effects of invigorating the spleen and stomach, eliminating accumulation of food, and enhancing immunity are highly targeted. This paper provides evidence for the research and development, mechanism research, and process improvement of spleen-invigorating health food with the homology of medicine and food in the future.

1 Introduction

“Homology of medicine and food” literally understood as the same origin of traditional Chinese medicine (TCM) and food, is a concept based on the understanding of the relationship between medicine and food in TCM. It has evolved into the ideology of food-based health promotion, which is reflected in dietary therapy, health preservation, and medicinal cuisine^[1]. The history of the dual use of medicine and food in China can be traced back to ancient times, as evidenced by the earliest expression of the concept in the *Inner Canon of Huangdi* (*Huang Di Nei Jing*, 《黄帝内经》), such as “grains, meat, fruits, and vegetables when consumed in moderation, nourish the body without causing harm” and “the ancient sages made soups, beverages, and liquors to prepare for unforeseen circumstances”. In the middle and ancient times, the way of health was a little weakened, and the disease could be cured via having some soup or liquor when the evil spirits of the outside world could often take advantage of the deficiency and hurt people^[2,3]. In TCM, the spleen is considered as the “foundation of the acquired constitution” and the “source of Qi-blood transformation”. The water and grain of transportation by spleen and stomach can maintain the “spirit and energy” of the human body and life activities, which are closely related to the functions of the digestive system, certain endocrine functions, and metabolism in modern medicine^[4]. The delicate transformation of water and grain by the spleen and stomach maintains the “essence, Qi, and spirit” of the human body and its vital activities. Dysfunction of the spleen and stomach is mainly characterized by poor appetite, abdominal distension, epigastric pain, loose stools, or conditions related to water dampness and phlegm^[5,6]. Therefore, invigorating spleen plays a crucial role in disease prevention and recovery^[7]. By 2020, the National Health Commission had approved 110 species of Chinese medicinal varieties with the homology of medicine and food^[8]. Among them, 47 species were recorded in the

Pharmacopoeia of the People's Republic of China (2020 edition), belonging to the spleen and stomach meridians, and exhibiting functions such as invigorating the spleen, replenishing the spleen, warming the middle, and eliminating dampness, including Shanzha (*Crataegi Fructus*), Shanyao (*Dioscoreae Rhizoma*), Baibiandou (*Lablab Semen Album*), Guanghuoxiang (*Pogostemonis Herba*), Xiaohuixiang (*Foeniculi Fructus*), Heye (*Nelumbinis Folium*), and Yiyiren (*Coicis Semen*)^[4,9].

Given the important role of spleen-invigorating healthcare products with homology of medicine and food in daily health preservation, the development and application of various types of spleen-invigorating health food with the homology of medicine, and these products in this category have become increasingly common. However, there is currently a lack of overall understanding of spleen-invigorating health food with the homology of medicine and food, including the number of patents, geographical and institutional distribution, technological and functional classifications, drug compositions, and active ingredients. To systematically summarize spleen-invigorating health food with the homology of medicine and food, this study searched the “Special Food Information Query Platform” of the State Administration for Market Regulation and the incoPat global patent database. The registered spleen-invigorating health food with the homology of medicine and food and related patent data in China were compiled. A literature-based quantitative and visual analysis was conducted to examine research and development trends, geographical and institutional distribution, technological and functional characteristics, major TCM, and active ingredients by utilizing R programming language and CytoScape software. This study aims to summarize and analyze the research, development, and application status of spleen-invigorating health food with the homology of medicine and food in China, and to provide evidence for finding the deficiency and condensing direction of the development of spleen-invigorating health food and its patent.

2 Data and methods

2.1 Data sources

The “Special Food Information Query Platform” of the State Administration for Market Regulation (<http://ypzxs.gsxt.gov.cn/specialfood/#/food>) and the incoPat global patent database (<https://www.incopat.com/>) were collected to compile data on registered spleen-invigorating health food with the homology of medicine and food and relevant patent information in China.

2.2 Retrieval strategy

The query platform of the State Administration for Market Regulation was searched using keywords such as “stomach” “spleen” and “digestion”. The incoPat global patent database was searched using specific technical and functional phrases including “spleen and stomach” “digestive system” “gastric mucosa” “gastrointestinal tract” “food stagnation” “abdominal pain and diarrhea” “immune enhancement” “appetite/digestion” “TCM syndrome” and “disease prevention”.

The technical and functional phrases encompassed various aspects regarding the spleen-invigorating and digestion-promoting effects, such as improving spleen and stomach function, enhancing digestion, alleviating spleen and stomach damage, and benefiting individuals with spleen and stomach weakness. Digestive enhancement consists of measures aiming at promoting gastric and intestinal digestion, enhancing digestion, optimizing spleen and stomach digestion, and facilitating efficient digestion and absorption. Gastric mucosal integrity includes stimulation of gastric mucosal repair, augmentation of gastric mucosal thickness, regulation of gastric fluid secretion, alleviation of gastric discomfort, and enhancement of digestive enzyme activity. Gastrointestinal functionality refers to enhancing gastric and intestinal digestion, expediting gastrointestinal motility, improving overall gastrointestinal function, regulating gastrointestinal processes, mitigating gastrointestinal irritability, rebalancing gut microecology, and detoxifying the intestinal tract. Alleviation of accumulated diet-related issues is to prevent and manage issues related to dietary accumulation, including anorexia and intestinal accumulations. Management of abdominal pain and loose stools are amelioration of abdominal pain and loose stools, alleviating gastrointestinal distress. Immune system enhancement represents measures to strengthen immune responses, enhance comprehensive immune function, elevate immune competence, and bolster overall bodily resilience. Appetite regulation and digestive stimulation denote approaches

aimed at improving appetite, stimulating metabolic processes, and accelerating nutrient metabolism. TCM syndrome type refers to syndrome types such as addressing spleen deficiency with Qi stagnation, treating deficient spleen and reduced appetite, mitigating dual deficiency of spleen and stomach, and fortifying spleen and stomach functions. Disease prevention stands for strategies encompassing preventive measures against a range of ailments, including various diseases, gastric coldness, and dampness-related conditions.

2.3 Inclusion criteria

The inclusion criteria are: (i) patents primarily related to “health food with the homology of medicine and food” or “medicine and food dual use” for invigorating spleen; (ii) application date ranging from January 1, 2000 to January 1, 2023.

2.4 Exclusion criteria

The exclusion criteria include any of the following: (i) duplicate applications and patents with incomplete information; (ii) patents related to preparation and method of spleen-invigorating foods; (iii) patents related to production equipment and devices; (iv) patents related to application methods and schemes; (v) patents unrelated to food; (vi) patents for digestive health products intended for animals; (vii) patents that did not align with the intended spleen-invigorating and digestion-promoting effects; (viii) patents that did not meet the healthcare food requirements.

2.5 Data extraction

Two independent reviewers read the patent titles and abstracts, and selected the relevant patents based on the inclusion and exclusion criteria. In cases where the decision failed to be made based on the title and abstract alone, the full content of the patent was reviewed. Discrepancies were resolved through discussion with a third researcher.

2.6 Standardization of data

The names of TCM were standardized based on the *Pharmacopoeia of the People's Republic of China* (2020 edition), *Compendium of Materia Medica*, and *Standards for Chinese Herbal Medicines*. Different names referring to the same herb or substance were unified. For example, “Huaishan” was standardized as “Shanyao (Dioscoreae Rhizoma)”, and “Damaiya” was unified into “Maiya (Hordei Fructus Germinatus)”. The patent's technical phrases were classified following the classification standards of the incoPat global patent database.

2.7 Statistical analysis

A database was established by using Excel 2019 to collect the data. R programming language was adopted for general descriptive literature analysis, including the analysis of the number of patents published annually, geographical distribution and applicant types, technical classifications, and major TCM components. Additionally, CytoScape software was employed for visual analysis of the relationships among TCM active ingredients, components, and functional effects.

3 Results

3.1 Basic characteristics of patents

In the initial search, a total of 1 367 patents related to spleen-invigorating health food with the homology of medicine and food were identified in China. After removing 389 duplicate varieties, 978 patents remained for the initial retrieval. Further refinement excluded 609 patents that were related to daily spleen-invigorating food preparation, preparation methods, production equipment and devices, application modes or schemes, non-food categories, animal-based digestive health products, and patents with inconsistent effects on spleen-invigorating and digestion-promoting. After the second screening, 369 patents remained. Additionally, 45 patents with repeated formulations and main ingredients were excluded, along with 39 patents that were not classified as health products. Finally, a total of 285 patents focusing on spleen-invigorating health food with the homology of medicine and food were selected for analysis (Figure 1).

3.2 The number of application, disclosure, and development trends of patents

The number of patent disclosures and their development trends can reflect the growth and changes in quantity over different periods, providing insights into the innovation capacity and development potential of the analyzed patents. A descriptive analysis of annual patent applications and disclosures from January 2000 to January 2023 revealed that the number of applications and disclosures of spleen-invigorating health food with the homology of medicine and food has increased annually in China since 2004. They reached a peak in 2015 - 2016 and experienced a slight decline, followed by a rebound in applications and disclosures in 2020 - 2021 (Figure 2).

3.3 Trends of patent disclosure among provinces of China

By analyzing the quantity and trends of patent technologies disclosed or granted in different periods from January 2000 to January 2023 among provinces, it was observed that the majority of provinces experienced an increase in patent disclosures during 2015 - 2016. Subsequently, from 2016 to 2023, the numbers gradually declined, but there was a slight rebound during 2021. Over the past 20 years, the top five provinces in terms of patent disclosures were Guangdong, Anhui, Jiangsu, Shandong, and Guangxi; among them, Guangdong Province has the highest number of patents (Figure 3).

3.4 Analysis of technical classification of patents among provinces of China

Based on the 10 major technical classification phrases defined by the incoPat global patent database, a frequency

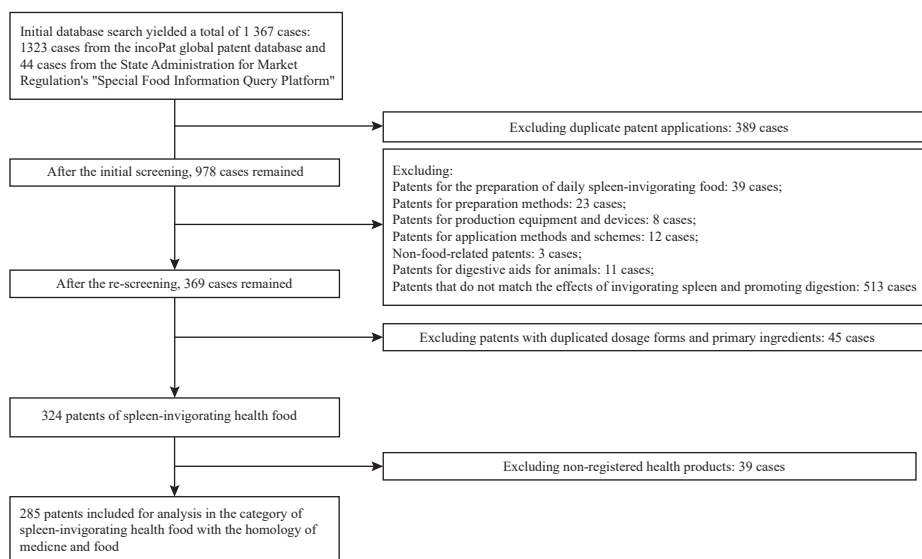


Figure 1 Patents retrieve flow chart of spleen-invigorating health food with the homology of medicine and food

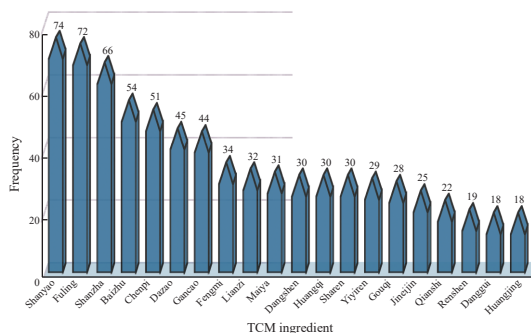


Figure 6 TCM ingredients in patents of spleen-invigorating health food with the homology of medicine and food

Macrocephalae Rhizoma), Chenpi (*Citri Reticulatae Pericarpium*), Dazao (*Jujubae Fructus*), Gancao (*Glycyrrhizae Radix et Rhizoma*), Fengmi (*Mel*), Lianzi (*Nelumbinis Semen*), Maiya (*Hordei Fructus Germinatus*), Dangshen (*Salviae Miltiorrhizae Radix et Rhizoma*), Huangqi (*Astragali Radix*), Sharen (*Amomi Fructus*), Yiyiren (*Coicis Semen*), Gouqi (*Lycii Fructus*), Jineijin (*Galli Gigerii Endothelium Corneum*), Qianshi (*Euryales Semen*), Renshen (*Ginseng Radix et Rhizoma*), Danggui (*Angelicae Sinensis Radix*), and Huangjing (*Polygonati Rhizoma*). Among them, Shanyao (*Dioscoreae Rhizoma*) had the highest frequency, occurring in 74 cases.

3.7 Distribution of technical efficacy of patents

Based on the technical efficacy phrases displayed in the incoPat global patent database, the technical efficacy of the 285 patents for spleen-invigorating health food with the homology of medicine and food was classified into 10 major categories: “related to immune enhancement” “related to digestion” “related to disease prevention” “related to appetite/digestion promotion” “related to gastrointestinal tract” “related to spleen and stomach” “related to gastric mucosa” “related to TCM patterns” “related to food stagnation” and “related to abdominal pain and diarrhea”. By analyzing the distribution of technical efficacy in these categories, it was found that the technical efficacy of over 20 patents was described as “immune enhancement” “digestion” “disease prevention” “appetite or digestion promotion” “gastrointestinal tract” and “spleen and stomach”. Among them, the most frequently mentioned category of technical efficacy was “immune enhancement”, appearing in a total of 71 patents (Figure 7).

3.8 The efficacy of active ingredients in TCM patents

For the top 10 frequently mentioned TCM in patents for spleen-invigorating health food with the homology of medicine and food, a total of 139 active ingredients were identified using the Traditional Chinese Medicine

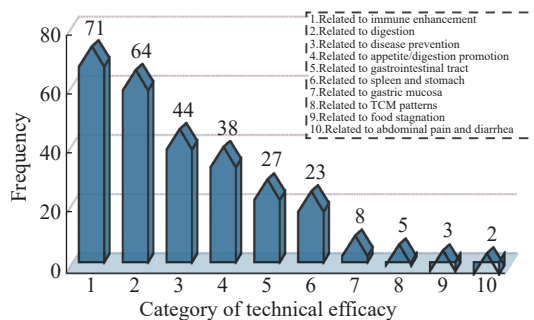


Figure 7 Distribution of patents technical efficacy of spleen-invigorating health food with the homology of medicine and food

Systems Pharmacology Database and Analysis Platform (TCMSP) with selection criteria of oral bioavailability (OB) at 30% or above and drug-likeness (DL) no less than 0.18. By referencing the *Pharmacopoeia of the People's Republic of China* (2020 edition), the efficacy of medicines was determined, and an active ingredient-medicine-efficacy network diagram was constructed (Figure 8). The corresponding analysis of active ingredients, medicines, and efficacy indicated that Gancao (*Glycyrrhizae Radix et Rhizoma*), Dangshen (*Codonopsis Radix*), and Shanyao (*Dioscoreae Rhizoma*) had the richest variety of active ingredients and efficacy. Their main efficacy included 10 categories: tonifying spleen and replenishing Qi, clearing heat and removing toxin, relieving cough, relieving pain and urgency, tonifying spleen and nourishing lung, nourishing blood and promoting fluid production, tonifying spleen and nourishing stomach, moistening lung and promoting fluid production, tonifying kidney and securing essence, and harmonizing various medicines (Figure 9). It could also enhance cellular immune response, suppress the secretion of gastric acid, increase gastrointestinal motility, reduce inflammatory response, and facilitate the healing of gastric ulcer through antioxidant mechanism [10-18] (Table 1). These patents had 139 active ingredients, including Taraxerol, Gadelaidic acid, 3'-Hydroxy-4'-O-Methylglabridin, Shinpterocarpin, Licoagrocarpin, 2-[(3R)-8,8-dimethyl-3,4-dihydro-2H-pyrano[6,5-f]chromen-3-yl]-5-methoxyphenol, Kanzonol F, 7-Methoxy-2-methyl isoflavone, Medicarpin, Xambioona Stigmasterol, Isofucosterol, and 24-Methylcholest-5-enyl-3 β -O-glucopyranoside. These active ingredients were reinputted into TCMSP, and the results revealed active ingredients' associations with 16 gastrointestinal diseases, including inflammatory diseases, Crohn's disease, colorectal tumors, gastrointestinal stromal tumors, radiation enteropathy, inflammatory bowel disease, ulcerative colitis, gastrointestinal cancers, colon cancer, Peutz-Jeghers syndrome, irritable bowel syndrome, diarrhea, postoperative nausea and vomiting, hereditary polyposis syndrome, gastrointestinal ulcers, and amoebiasis.

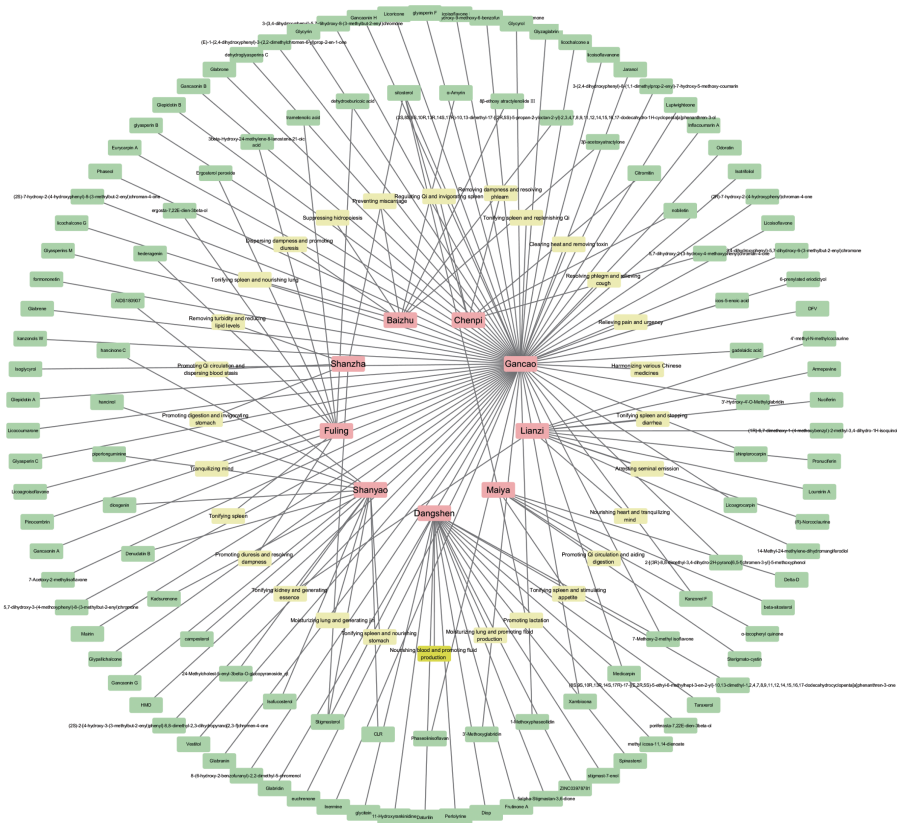


Figure 8 Network diagram of efficacy of active ingredients in TCM patents of spleen-invigorating health food with the homology of medicine and food
 Red for TCM, yellow for efficacy, and green for active ingredients.

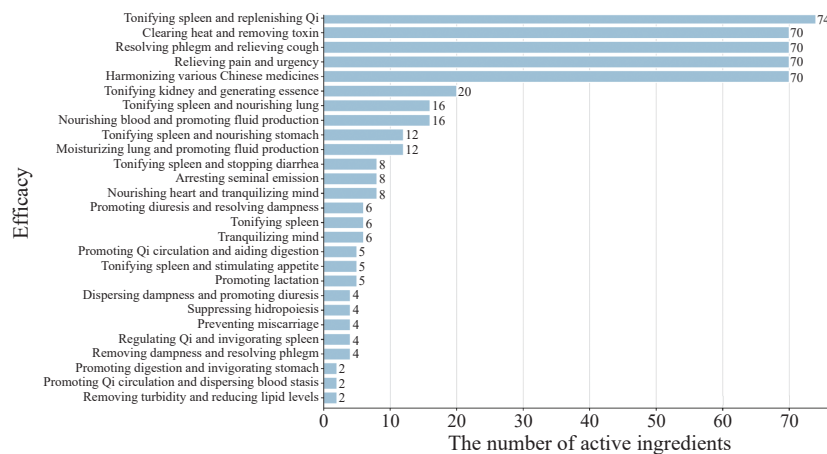


Figure 9 Frequency of active ingredients and efficacy of spleen-invigorating health food with the homology of medicine and food

Table 1 The spleen-invigorating health food with the homology of medicine and food product extracts and mechanism

Source	Effective component	Spleen-strengthening activity/Mechanism	Reference
Shanyao (Dioscoreae Rhizoma)	Phenolic compound, Chinese yam polysaccharide, dioscin, allantoin, choline, and flavonoids	Tonifying spleen and nourishing stomach, moistening lungs and promoting fluid production, tonifying kidney and generating essence, enhancing growth performance and cellular immune response, suppressing the secretion of gastric acid, and increasing gastrointestinal motility	[10]
Fuling (Poria)	Polysaccharides, triterpenoids, fatty acids, sterols, and enzymes	Promoting diuresis and resolving dampness, tonifying spleen, tranquilizing mind, and promoting digestive function and water metabolism	[11]

Table 1 Continued

Source	Effective component	Spleen-strengthening activity/Mechanism	Reference
Shanzha (Crataegi Fructus)	Vitexin7-glucoside, 20-hexadecanoylingenol, and suchilactone	Promoting digestion and invigorating stomach, promoting Qi circulation and dispersing blood stasis, removing turbidity and reducing lipid levels, reducing inflammatory response, increasing intestinal moisture, and promoting intestinal motility	[12]
Baizhu (Atractylodis Macrocephalae Rhizome)	5-CQA, 4-CQA, 1,3-DiCQA, 3,4-DiCQA, 4,5-DiCQA, and atractylenolide I/II/III	Tonifying spleen and replenishing Qi, dispersing dampness and promoting diuresis, suppressing hidropoiesis, and preventing miscarriage	[13]
Chenpi (Citri Reticulatae Pericarpium)	Hesperidin, tangeretin, sitosterol, and naringetol	Regulating Qi and invigorating spleen, removing dampness and resolving phlegm, suppressing inflammatory responses, and protecting against peptic ulcer	[14]
Gancao (Glycyrrhizae Radix et Rhizoma)	Glycyrrhetic acid, glycyrrhizic acid, liquiritin, isoliquiritin, and glabridin	Tonifying spleen and replenishing Qi, clearing heat and removing toxin, resolving phlegm and relieving cough, relieving pain and urgency, harmonizing various Chinese medicines, and suppressing inflammatory responses	[15]
Lianzi (Nelumbinis Semen)	Roemerine, norcoclaurine, pronociferine, and benzyloquinoline alkaloids	Tonifying spleen and stopping diarrhea, arresting seminal emission, tonifying kidney and promoting essence, and nourishing heart and tranquilizing mind	[16]
Maiya (Hordei Fructus Germinates)	δ -D, β -sitosterol, sitosterol, α -tocopheryl quinone, and sterigmatocystin	Promoting Qi circulation and aiding digestion, tonifying spleen and stimulating appetite, and promoting lactation	[17]
Dangshen (Codonopsis Radix)	Luteolin, stigmasta-5,22-dien-3-one, taraxerone, nicotinic acid, phenylalanine, phenylic acid, α -curcumene, nicotine, enecalinal, 7-methoxy-2-methyl isoflavone, glycitein, α -pinene, stigmasterol, β -curcumene, and 2,4,4-trimethyl-1-pentene	Tonifying spleen and nourishing lung, nourishing blood and promoting fluid production, facilitating the healing of gastric ulcer through antioxidant mechanism, protecting the integrity of cell membrane structure and function, inhibiting gastric acid secretion, and adding gastric mucus secretion	[18]

4 Discussion

4.1 Pathogenesis of Chinese and western medicine of spleen dysfunction

Spleen deficiency, characterized by dysregulation or weakness of spleen function, disrupts the harmonious circulation of Qi and blood within the body. Various factors, including irregular dietary habits, excessive stress, external pathogenic factors, a sedentary lifestyle, and congenital deficiencies can contribute to spleen deficiency. Moreover, the spleen's affinity for dryness and aversion to dampness makes it susceptible to imbalance when dampness accumulates both internally and externally. Spleen weakness causes insufficient digestive and transformative functions, resulting in disrupted ascension and descent, hindered clear Yang and descending turbid Qi, compromised bioavailability of Qi and blood, and imbalanced Yin and Yang. Current medical research has uncovered the intricate links between spleen deficiency and mechanisms such as recurrent infections induced by sustained inflammation, metabolic disturbances, and immune suppression [19]. Spleen dysfunction significantly impacted the absorption, digestion, and nutritional metabolism of the gastrointestinal system [20], often manifesting as digestive symptoms including abdominal distension, belching, gastric pain, and loose

stools. These symptoms are commonly accompanied by, among other systemic manifestations, recurrent fever, dizziness, insomnia, depression, anxiety, lack of concentration, and anemia [21-23]. Notably, spleen-invigorating health food with the homology of medicine and food plays an important role in the prevention and recovery of diseases, such as inflammation, metabolism, digestive system, and immune system in the body.

4.2 Innovation and development encourage the continuous growth of patents

This study conducted a systematic analysis of the patent landscape of spleen-invigorating health food with the homology of medicine and food in China. Over the past two decades, there has been a consistent rise in patent registrations for spleen-invigorating health food, with the peak observed in 2015 and 2016, followed by a slight decline between 2017 and 2021. The observed fluctuations in patent registrations might be attributed to specific regulatory changes that occurred during the study period. Notably, the issuance of announcements by the China Food and Drug Administration (CFDA) in 2015 "Announcement of Self-Inspection and Verification of Drug Clinical Trial Data" [24], as well as the "Administrative Measures for Registration and Filing of Health Food" in 2016 [25], introduced more precise and stringent requirements for

the registration of medicinal and health food. These regulatory adjustments could have contributed to the variation in patent numbers. Furthermore, the cyclical nature of market development within the spleen-invigorating health food with the homology of medicine and food might have played a part. Initially, increased innovation and investment might have driven a surge in patent applications. Subsequently, as technologies became more widespread and competition intensified, the number of registrations might have experienced a temporary decline. However, a comprehensive analysis of registration trends over the past two decades has indicated that the enthusiasm for developing spleen-invigorating health food remains unwavering. Institutions continue to maintain a positive outlook on the long-term prospects of this field. As such, the realm of spleen-invigorating health food with the homology of medicine and food necessitates a sustained commitment to innovation and ongoing renewal to meet market demands and remain competitive.

4.3 Strengthening cooperation with scientific research institutions by enterprises necessary for achieving the transformation of outputs

An insightful examination of regional patent disclosure trends, applicant profiles, and technological efficacy reveals a predominant concentration of registrations in the eastern, southern, and coastal areas of China, featured with Guangdong, Guangxi, Anhui, Jiangsu, and Shandong. The abundance of resources and technological prowess in the coastal and southeastern areas, buoyed by robust economies and open markets, creates a favorable environment for the development of spleen-invigorating health food. These provinces, characterized by early adoption of health care by TCM, enjoy higher levels of public health literacy and acceptance of holistic health maintenance. Enterprises, as a pivotal driving force behind innovation, account for nearly half of the total patent registrations. Enterprises represent the principal agents of innovation within the domain of spleen-invigorating herbal products.

Comparative analysis of patent technical classifications across various provinces can offer invaluable insights for relevant governmental bodies, enterprises, and research institutions. This analysis is conducive to comprehending the unique strengths and characteristics of different locales, thereby facilitating the formulation of targeted developmental strategies. Such strategies are instrumental in driving innovation and fostering growth within the industry of spleen-invigorating herbal products. Numerous provinces and cities, steeping in the history of TCM and being endowed with abundant natural resources, possess a diverse array of authentic herbal ingredients. Examples include the Mudanpi (Moutan Cortex) from Anhui Province, Bohe (Menthae Haplocalycis

Herba), Cangzhu (Atractylodis Rhizoma), Shihu (Dendrobii Caulis), Taizishen (Pesudostellariae Radix), and Chanchu (Toad Venom) from Jiangsu Province, Ejiao (Asini Corii Colla) from Shandong Province, and Rougui (Cinnamomi Cortex), Sanqi (Notoginseng Radix et Rhizoma), and Gejie (Gecko) from Guangxi Province^[26]. This rich repository of native Chinese herbal resources offers a competitive edge in research and innovation within this field. In response, the governments should promulgate supportive policies to foster a nurturing environment. Economic prosperity and robust technological capabilities in certain areas empower them with a leading edge in the research and development of health food with the homology of medicine and food, positioning them at the forefront of spleen-invigorating health food innovation and patent applications. Provinces with a rich history and abundant resources in TCM possess distinct advantages in local Chinese herbal resources, which, when harnessed through collaborative efforts between enterprises and research institutions, integration of resources and technologies, can drive the advancement and innovation of spleen-invigorating health food with the homology of medicine and food.

4.4 Mining of monomer active ingredients of the spleen-invigorating health food requires further investigation

In analyzing the main constituents and therapeutic components of the 285 registered patents, the results indicate that the dominant ingredients include Shanyao (Dioscoreae Rhizoma), Fuling (Poria), Shanzha (Crataegi Fructus), Baizhu (Atractylodis Macrocephalae Rhizoma), Chenpi (Citri Reticulatae Pericarpium), Dazao (Jujubae Fructus), and Gancao (Glycyrrhizae Radix et Rhizoma). These ingredients are characterized by well-defined compositional and functional attributes. Their roles encompass spleen invigorating, digestion enhancement, antioxidant properties, lipid regulation, sleep improvement, fatigue relief, and immune enhancement^[27, 28]. High-frequency utilization of these complex herbal constituents highlights their multifaceted nature and diverse target interactions. At present, the spleen-invigorating health food authorized by CFDA primarily describes its active components as flavonoids, with some containing polysaccharides and vitamins. The spleen-invigorating health food with the homology of medicine and food continues to garner attention from both biopharmaceutical enterprises and the public, with patent development following closely behind other applications such as tonifying Qi and nourishing blood, relieving pain and anti-inflammation^[29, 30]. Nevertheless, further research is needed to comprehensively explore the screening and optimization of drug compatibility and the mining of monomer active ingredients with specific effects of spleen-invigorating health food with the homology of

medicine and food, the pharmacological analysis of patent connotation, and the determination of component content are still poor. Additionally, the research and development of health food with the homology of medicine and food in China are still at the initial stage, and there is still a big gap in the application of spleen-invigorating health food in the market, such as the lack of high brand influence, good therapeutic efficacy, and mature technology for spleen-invigorating health food with the homology of medicine and food [31-33].

5 Conclusion

To sum up, the research and development of spleen-invigorating health food with the homology of medicine and food receive increasing attention. The main drug composition and functional ingredients of spleen-invigorating health food remain relatively clear, and the technical efficacy of invigorating spleen and stomach, eliminating food and enhancing immunity are highly targeted. The research and development of health food with the homology of medicine and food still require the government to formulate and enforce a better positive policy. Enterprises and research institutions should strengthen cooperation, basic research, and health industry market transformation. Moreover, they should further explore the composition of the spleen-invigorating health food optimization and specificity effect, improve the process of research and development, pay attention to individual differences and the needs of different individuals, and design a more targeted spleen-invigorating health food.

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Competing interests

The authors declare no conflict of interest.

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基于文献计量学的药食同源健脾类保健食品专利的研究趋势与发展前景分析： 2000 - 2022 年

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【摘要】目的 为了分析我国药食同源健脾类保健食品专利的研究现状与发展趋势,为中医药健脾类健康产品的研发提供思路与参考依据。**方法** 检索国家市场监督管理总局网站“特殊食品信息查询平台”及 incoPat 全球专利数据库,基于文献计量学方法梳理我国已注册的药食同源健脾类保健食品、专利相关数据信息,分析我国健脾类保健食品专利研发数量、地域与机构,技术与功效分类、主要药物组成和有效成分等,应用 R 语言与 Cytoscape 软件对筛选后的专利数据进行可视化分析。**结果** 共纳入分析药食同源健脾类保健食品专利 285 例。自 2012 年起,我国药食同源健脾类保健食品注册专利数量大幅增加;在过去 20 年中,专利公开数量排名前 5 的省份为广东、安徽、江苏、山东与广西;超过 20 例的专利中的技术功效短语有“关于增强免疫类”“关于消化类”“关于预防疾病类”等;专利注册以企业研发为主导,科研机构和个人申请为辅,主要针对食品或食料的一般保存,化合物或药物制剂的特定治疗活性等配制品的研发;285 例专利中,排名前 10 的药食同源健脾类保健食品主要原料药为山药、茯苓、山楂、白术、陈皮、大枣、甘草、蜂蜜、麦芽与党参,主要功效为补脾益气、健脾益肺、养血生津、补脾养胃等。**结论** 药食同源健脾类保健食品的主要药物组成、功能性成分较为明确,健脾胃、消积食、增强免疫力等技术功效靶向性较强。本文为后续药食同源健脾类保健食品产品研发、机理研究和工艺改进提供了参考依据。

【关键词】 中医药;药食同源;健脾;保健食品;专利;文献计量学;可视化分析