




## Guideline

# Guideline for Traditional Chinese Medicine Diagnosis and Treatment of Primary Liver Cancer



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## Abstract

Primary liver cancer is one of the most common malignant tumors in China, which seriously threatens people's lives and health. In recent years, with the advancement of basic and clinical research, the diagnosis and treatment methods for primary liver cancer have been continually enriched. Traditional Chinese medicine (TCM) has played an important role in the diagnosis and treatment of primary liver cancer, but there is no unified standard for differentiation and treatment, and efficacy evaluation. In order to further standardize the TCM diagnosis and treatment of primary liver cancer, according to the requirements of TCM standardization and related technical guidance documents, the drafting team compiled this guideline through literature research, expert interviews, questionnaire surveys, consensus meetings, etc., for reference by clinicians. This guideline is approved and issued by the China Association of Chinese Medicine, standard number: T/CACM 1575-2024.

**Keywords:** Primary liver cancer; Traditional Chinese medicine; TCM; Guidelines; Diagnosis; Treatment; Evidence-based medicine.

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## Introduction

Primary liver cancer (PLC) currently ranks as the fourth most common malignancy and the second leading cause of cancer-related mortality in China, posing a severe threat to public health. According to statistics from the National Cancer Center, China recorded

410,000 new cases and 390,000 deaths of PLC in 2020. These figures represent the second and fifth leading causes of cancer death among Chinese males and females, respectively. The management of PLC necessitates multidisciplinary collaboration. Optimal long-term outcomes can be achieved through the sequential and standardized application of therapies, including liver resection, liver transplantation, ablation therapy, transarterial chemoembolization (TACE), radiotherapy, systemic antitumor therapy, and Traditional Chinese Medicine (TCM).

TCM possesses extensive clinical experience in treating PLC. Based on the characteristics of etiology and pathogenesis, distinct therapeutic methods are employed across various stages according to specific TCM pattern differentiation. TCM has demonstrated significant clinical efficacy in relieving symptoms, reducing adverse reactions, prolonging survival, and improving the quality of life (QOL) for patients with liver cancer. However, there remains a lack of unified standards for pattern differentiation and efficacy evaluation, as well as a deficiency of high-level evidence-based medical data.

To further standardize the TCM diagnosis and treatment of PLC, the drafting group developed these clinical practice guidelines. The guideline was developed using evidence-based medical methodologies, integrating systematic reviews and meta-analyses of the literature, expert experience, and recent advances in the prevention and treatment of PLC with TCM.

## Definitions

**PLC:** A malignancy originating within the liver, encompassing three distinct pathological types: hepatocellular carcinoma (HCC), intrahepatic cholangiocarcinoma (ICC), and combined HCC-ICC.

**Ganji (liver accumulation):** A category of accumulation (ji) disease characterized by the obstruction of liver collaterals (gan-luo, referring to the finer network of microvessels and functional pathways) due to various etiologies, leading to the loss of the liver's characteristic softness and the impairment of its free-flowing function (shuxie, often associated with neuroendocrine-immune regulation and metabolic homeostasis). Clinical manifestations primarily include right hypochondriac pain, hypochondriac masses, abdominal distension, anorexia, and symptoms associated with liver stasis.<sup>1</sup>

**Zhengjia (abdominal mass):** The presence of palpable, tangible masses within the abdominal cavity, typically formed by the entanglement of "pathogens with form", such as blood stasis (reflecting microcirculatory disturbances and pro-fibrotic signaling), parasite accumulation (chongji), food stagnation, dry stools (zaoshi), or phlegm coagulation (reflecting chronic inflammatory and metabolic waste states).<sup>1</sup>

**Post-embolization syndrome (PES):** A cluster of adverse reactions occurring in patients with PLC following TACE. Common clinical presentations include fever, nausea, vomiting, pain in the liver region, abdominal distension, and anorexia.<sup>2</sup>

## TCM disease diagnosis

In TCM, PLC is classified under categories such as Ganji (liver accumulation), Zhengjia (abdominal masses), and Gancai (liver cancer).

## TCM etiology and pathogenesis

The development of liver cancer is primarily attributed to con-

stitutional deficiency, chronic debility, emotional depression, dietary irregularities, excessive alcohol consumption, or exposure to pathogenic toxins. These factors lead to a state of root deficiency and branch excess (zheng deficiency and pathogenic factors excess). Prolonged entanglement of Qi stagnation, blood stasis, phlegm-dampness, and heat-toxin eventually culminates in the formation of "accumulation" (ji). As stated in the Yizong Bidu (Guided Specialties of Medicine): "The formation of accumulation occurs when Zheng Qi is insufficient, allowing pathogenic factors to reside".

The etiology and pathogenesis of liver cancer are complex, with "deficiency" serving as the fundamental root—the disease arises from deficiency and subsequently leads to excess. Pathologically, it manifests as internal accumulation of turbid toxins, Qi stagnation, blood stasis, and obstruction of the collaterals. In the early stages, the deficiency of Qi, blood, Yin, and Yang may still struggle against the excesses of toxins, stasis, phlegm, and stagnation. In the advanced stages, the zang-fu organs (TCM functional organ systems, often corresponding to but not identical with anatomical organs), specifically the liver, spleen, and kidney, are all compromised, leading to the depletion of the sources of Qi and blood production. During this phase, virulent pathogenic toxins flourish, resulting in various complications such as masses, Zhengjia (abdominal masses and accumulations), jaundice, tympanites (guzhang, abdominal swelling), and hemorrhagic syndromes.

Consequently, clinical manifestations of liver cancer vary, presenting diverse TCM patterns. The overarching therapeutic principle is to strengthen the body's resistance and eliminate pathogenic factors (fu zheng qu xie, focusing on holistic regulation and multi-target intervention). Strengthening resistance involves restoring organ functions such as tonifying the spleen (improving metabolic function and nutritional status), supplementing Qi, nourishing Yin, supplementing blood, and warming Yang. Eliminating pathogens involves removing pathological products by promoting Qi movement, activating blood and resolving stasis (ameliorating microcirculation and inhibiting pro-fibrotic pathways), transforming dampness, detoxifying, clearing heat, and dissipating nodules (promoting the resolution of fibrotic lesions). Clinical practice requires balanced management of the relationship between strengthening resistance and eliminating pathogens.

## TCM pattern diagnosis

### Overview

With reference to the Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2022 Edition) and the Expert Consensus on Integrative Chinese and Western Medicine Interventional Diagnosis and Treatment for Primary Liver Cancer,<sup>3</sup> a comprehensive analysis was conducted on clinical research literature regarding TCM and integrative medicine treatments for PLC published in domestic biomedical journals from 1984 to 2022. The TCM pattern diagnostic standards were statistically determined based on occurrence frequency and clinical case applications. Detailed contents are provided below.

### Liver Qi stagnation pattern (*Gan Qi Yu Jie Zheng*)

**Clinical manifestations:** Distending pain in the hypochondrium with a wandering location, distension and fullness in the epigastrium and abdomen, chest oppression, frequent sighing, irritability, and susceptibility to anger.

*Tongue and pulse:* Pale-red tongue with a thin white coating; wiry pulse.

#### **Qi stagnation and blood stasis pattern (Qi Zhi Xue Yu Zheng)**

*Clinical manifestations:* Distending oppression and piercing pain in the chest and hypochondrium, fixed pain aggravated by pressure, or stabbing pain in the chest and hypochondrium that worsens at night. Presence of upper abdominal masses, liver palms, spider nevi, and varicose veins on the abdominal wall; in severe cases, squamous and dry skin (ji fu jia cuo, reflecting severe microcirculatory failure and malnutrition).

*Tongue and pulse:* Dark or dusky-red tongue with ecchymosis or petechiae; sublingual veins are prolonged, thickened, or tortuous. Thin white or thin yellow tongue coating; fine-wiry or fine-choppy and weak pulse.

#### **Damp-heat and toxin accumulation pattern (Shi Re Du Yun Zheng)**

*Clinical manifestations:* Burning and distending pain in the right hypochondrium, anorexia, epigastric oppression, constipation or sticky and impeded stool, fever, bitter taste in the mouth, dry mouth, vexation, irritability, and yellow urine (reflecting acute inflammatory and oxidative stress states).

*Tongue and pulse:* Red tongue with a yellow, greasy coating; rapid or slippery pulse.

#### **Liver depression and spleen deficiency pattern (Gan Yu Pi Xu Zheng)**

*Clinical manifestations:* Distension and fullness in the chest and abdomen, emaciation, fatigue, lassitude, shortness of breath, abdominal distension, and poor appetite (reflecting impaired digestion and metabolic dysfunction). Dry mouth without desire for fluids, loose stools with increased frequency, and scanty yellow urine. In severe cases, ascites, jaundice, and edema of the lower extremities may occur.

*Tongue and pulse:* Enlarged tongue body with a white coating; fine-wiry pulse.

#### **Liver and kidney Yin deficiency pattern (Gan Shen Yin Xu Zheng)**

*Clinical manifestations:* Malar flushing and dry mouth, tidal fever or feverish sensation in the palms and soles (five-center heat), restlessness, and insomnia. Anorexia, constipation, abdominal distension, and abdominal enlargement (ascites) with prominent abdominal veins. Emaciation of the four limbs with edema, shortness of breath, and tachypnea. In severe cases, coma and delirium, gingival bleeding (chi nu), epistaxis (bi nu), or hematochezia and hematuria.

*Tongue and pulse:* Red tongue with scanty coating; fine, rapid, and weak pulse.

### **Therapeutic goals of TCM**

The therapeutic approach integrates disease-pattern combination and pattern differentiation and treatment (bian zheng lun zhi), adhering to the principles of strengthening body resistance and eliminating pathogens, as well as treating both the branch and the root. The primary objectives include: ameliorating clinical symptoms and improving tumor-related biomarkers, reducing tumor recurrence, enhancing the QOL for patients, and prolonging overall survival (OS).

### **Therapeutic regimens**

#### **Western medical treatment**

Patients who meet the clinical diagnostic criteria for PLC as defined in the Guidelines for Diagnosis and Treatment of Primary Liver Cancer and who require treatment may select therapeutic options based on their specific condition.<sup>3</sup> These include surgical intervention, ablation therapy, TACE, radiotherapy, and systemic antitumor therapy [targeted therapy, immunotherapy, systemic chemotherapy, and other treatments (antiviral and hepatoprotective therapy, symptomatic supportive treatment)]. Specific protocols may refer to the Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2022 Edition).<sup>3</sup>

#### **TCM pattern differentiation and treatment**

##### **Overview**

Based on the analysis of clinical research literature regarding TCM and integrative medicine treatments for PLC published in domestic biomedical journals from 1984 to 2022, and with reference to the Guidelines of Diagnosis and Therapy in Oncology with Traditional Chinese Medicine,<sup>4</sup> the Guidelines for the Diagnosis and Treatment of Primary Liver Cancer with Integrated Traditional Chinese and Western Medicine,<sup>5</sup> and the RECIST and mRECIST criteria for efficacy evaluation,<sup>6,7</sup> the following therapeutic courses are established:

- *Symptomatic treatment:* The course of treatment for symptomatic relief is approximately 7 to 14 days;
- *Other therapeutic goals:* For other treatment objectives, one therapeutic course generally lasts 4 to 8 weeks;
- *Follow-up:* Stage-based follow-ups are required.

##### **Liver Qi stagnation pattern**

*Therapeutic principle:* Soothing the liver, relieving depression, regulating Qi, and dissipating nodules. *Recommended formula:* Modified Chaihu Shugan San.<sup>8-12</sup>

*Composition:* Chenpi (Citri Reticulatae Pericarpium), Chaihu (Bupleuri Radix), Chuanxiong (Chuanxiong Rhizoma), Xiangfu (Cyperus Rhizoma), Zhi Ke (Aurantii Fructus), Shaoyao (Paeoniae Radix), Gancao (Glycyrrhizae Radix), etc.

*Evidence level:* Grade II, strong recommendation.

*Clinical significance:* Combining this formula with TACE improves the objective response rate (ORR) and QOL.<sup>8-11</sup> When combined with fentanyl patches, it significantly reduces the dosage of fentanyl required for cancer pain.<sup>12</sup>

##### **Qi stagnation and blood stasis pattern**

*Therapeutic principle:* Activating blood, resolving stasis, softening hardness, and dissipating nodules.

*Recommended formula:* Modified Xuefu Zhuyu Tang combined with Bijia Fen Wan.<sup>13,14</sup>

*Composition:* Taoren (Persicae Semen), Honghua (Carthami Flos), Danggui (Angelicae Sinensis Radix), Shengdi Huang (Rehmanniae Radix), Niuxi (Achyranthis Bidentatae Radix), Chuanxiong (Chuanxiong Rhizoma), Jiege (Platycodonis Radix), Chishaoyao (Paeoniae Radix Rubra), Zhi Ke (Aurantii Fructus), Gancao (Glycyrrhizae Radix), Chaihu (Bupleuri Radix), Bijia (Trionycis Carapax), Tubiechong (Eupolyphaga), Fengchao (Vespae Nidus), Huangqin (Scutellariae Radix), Ganjiang (Zingiberis Rhizoma), Dahuang (Rhei Radix et Rhizoma), Guizhi (Cinnamomi Ramulus), Shigao (Gypsum Fibrosum), Houpo (Magnoliae Officinalis Cortex), Banxia (Pinelliae Rhizoma), Renshen (Ginseng

Radix et Rhizoma), Ejiao (Asini Corii Colla), etc.

*Evidence level:* Grade III, strong recommendation.

*Clinical significance:* This regimen effectively alleviates post-TACE pain in the liver region and enhances QOL.<sup>13</sup> When combined with XELOX chemotherapy, it significantly increases the ORR.<sup>14</sup>

### Damp-heat and toxin accumulation pattern (Shi Re Du Yun Zheng)

*Therapeutic principle:* Clearing heat, promoting diuresis, detoxifying, and dissipating masses.

*Recommended formula:* Modified Yinchenhao Tang combined with Wuling San.<sup>15–17</sup>

*Composition:* Yinchenhao (Artemisiae Scopariae Herba), Dahuang (Rhei Radix et Rhizoma), Zhizi (Gardeniae Fructus), Zhuling (Polyporus), Fuling (Poria), Baizhu (Atractylodis Macrocephalae Rhizoma), Zexie (Alismatis Rhizoma), and Guizhi (Cinnamomi Ramulus).

*Evidence level:* Grade III, strong recommendation.

*Clinical significance:* Combining modified Yinchenhao Tang with conventional hepatoprotective and jaundice-reducing therapies for PLC-related jaundice increases the effective rate and significantly reduces total bilirubin levels.

### Liver depression and spleen deficiency pattern (Gan Yu Pi Xu Zheng)

*Therapeutic principle:* Soothing the liver, strengthening the spleen, regulating Qi, and dissipating masses.

*Recommended formula:* Modified Xiaoyao San.<sup>18–25</sup>

*Composition:* Chaihu (Bupleuri Radix), Danggui (Angelicae Sinensis Radix), Baishao (Paeoniae Radix Alba), Dangshen (Codonopsis Radix), Baizhu (Atractylodis Macrocephalae Rhizoma), Fuling (Poria), and Gancao (Glycyrrhizae Radix).

*Evidence level:* Grade II, strong recommendation.

*Clinical significance:* Combining Xiaoyao San with TACE or ablation therapy improves the ORR and enhances QOL. Furthermore, this integration reduces the incidence of postoperative adverse reactions, such as nausea, vomiting, and pain in the liver region.

### Liver and kidney Yin deficiency pattern (Gan Shen Yin Xu Zheng)

*Therapeutic principle:* Nourishing the liver and kidney, resolving stasis, and dissipating masses.

*Recommended formula:* Modified Yiguan Jian.<sup>26–29</sup>

*Composition:* Beishashen (Glehniae Radix), Maidong (Ophiopogonis Radix), Danggui (Angelicae Sinensis Radix), Shengdi Huang (Rehmanniae Radix), Gouqizi (Lycii Fructus), and Chuanlianzi (Toosendan Fructus).

*Evidence level:* Grade III, strong recommendation.

*Clinical significance:* Combining this formula with radiotherapy improves the ORR. When integrated with TACE or ablation therapy, it enhances QOL, ameliorates liver injury, and reduces alpha-fetoprotein (AFP) levels. Furthermore, its combination with apatinib mesylate increases antitumor efficacy and prolongs OS.

### Classic formulas (Jingdian Mingfang)

#### Xiangsha Liu junzi Tang

Combining this formula with TACE reduces the incidence of PES symptoms, such as upper abdominal pain, nausea, and vomiting (Evidence level: Grade III, strong recommendation).<sup>30</sup>

#### Xiaochaihu Tang

Combining this formula with TACE/ablation improves antitumor efficacy, prolongs progression-free survival, and enhances QOL (Evidence level: Grade II, strong recommendation).<sup>31–34</sup>

It ameliorates PES symptoms like fever, nausea, vomiting, and liver region pain (Evidence level: Grade II, strong recommendation).<sup>32–35</sup>

When combined with sorafenib, it reduces the incidence of adverse reactions such as diarrhea and proteinuria (Evidence level: Grade III, strong recommendation).<sup>36</sup>

#### Longdan Xiegan Tang

Combining this formula with TACE improves PES symptoms, including fever, diarrhea, nausea, vomiting, and liver region pain (Evidence level: Grade III, weak recommendation).<sup>37,38</sup>

#### Simo Tang:

Combining this formula with TACE improves gastrointestinal function and ameliorates constipation in patients with PLC (Evidence level: Grade III, strong recommendation).<sup>39,40</sup>

### Chinese patent medicine (CPM) therapy

#### Overview

The application of CPMs in the treatment of PLC is characterized as being “simple, convenient, inexpensive, and effective”. CPMs are categorized into three major types based on their therapeutic mechanisms:

- *Category I:* Strengthening Body Resistance (Fu Zheng Gu Ben): These medicines supplement Qi, strengthen the Spleen, nourish Qi and blood, tonify the Kidney, replenish essence, nourish Yin, and moisten dryness. Common examples include Kangai Injection, Shenqi Fuzheng Injection, Yangzheng Xiaoji Capsules, Shengmai Injection, and Shenmai Injection.
- *Category II:* Eliminating Pathogens and Antitumor Efficacy (Gong Xie Yi Liu): These medicines regulate Qi, activate blood, clear heat, detoxify, soften hardness, dissipate nodules, transform phlegm, and remove dampness, effectively “attacking toxins with toxins” (yi du gong du). Common examples include Huisheng Oral Liquid, Fufang Banmao Capsules, Jinlong Capsules, Fufang Kushen Injection, Huachansu (Cinobufacini), and Xiaoaiping (Tongguanteng) Injection.
- *Category III:* Integrated Strengthening and Antitumor Efficacy (Fu Zheng Yi Liu): These medicines aim to support Zheng Qi, detoxify, and dissipate nodules. Common examples include Huaier Granules, Cidan Capsules, Ganfule Capsules/Tablets, and Kanglaite Injection.

### Integrated application of CPMs following surgical resection

Reducing postoperative recurrence and prolonging survival

The five-year recurrence rate for PLC following surgical resection is approximately 40–70%, primarily manifesting as intrahepatic recurrence.<sup>41</sup> Medications proven to reduce the postoperative recurrence rate and prolong OS include: Huaier Granules (Evidence level: Grade I, strong recommendation),<sup>42–44</sup> Jinlong Capsules (Evidence level: Grade II, strong recommendation),<sup>45,46</sup> Huachansu Capsules (Evidence level: Grade II, strong recommendation),<sup>47</sup> and Compound Kushen Injection (Evidence level: Grade III, weak recommendation).<sup>48</sup> The roles of Chinese patent medicines in postoperative management are summarized in Supplementary Table 1.

### Immunomodulation

Following surgical resection of PLC, the administration of medications such as Jinlong Capsules (Evidence level: Grade II, strong recommendation),<sup>46</sup> Shenqi Fuzheng Injection (Evidence level: Grade II, strong recommendation),<sup>49,50</sup> and Compound Kushen Injection (Evidence level: Grade III, weak recommendation) can significantly elevate the levels of CD4<sup>+</sup> and CD4<sup>+</sup>/CD8<sup>+</sup> T-cell subpopulations.<sup>48</sup> Additionally, Huachansu Capsules (Evidence level: Grade II, strong recommendation) can increase levels of complement C3, complement C4, IgA, IgM, and IgG, thereby enhancing host immunity.<sup>47</sup>

### Ameliorating postoperative adverse reactions

Medications such as Compound Kushen Injection (Evidence level: Grade III, weak recommendation),<sup>48</sup> Shengmai Injection (Evidence level: Grade III, strong recommendation),<sup>51</sup> and Shenqi Fuzheng Injection (Evidence level: Grade II, strong recommendation) can effectively improve liver function abnormalities following PLC resection.<sup>49,50</sup>

Shengmai Injection (Evidence level: Grade III, strong recommendation) significantly alleviates postoperative symptoms such as fatigue,<sup>51</sup> sweating, and shortness of breath, thereby shortening the duration of hospitalization.

### Improving postoperative QOL

The integrated application of Jinlong Capsules (Evidence level: Grade II, strong recommendation) following surgical resection of PLC can enhance the QOL for patients.<sup>45,46</sup>

### Integrated application of CPMs with TACE/ablation

The therapeutic effects of Chinese patent medicines combined with TACE or ablation, including improvements in objective response rate, survival, quality of life, immune function, and adverse reactions, are summarized in Supplementary Table 2.

### Enhancing therapeutic efficacy

#### Improving ORR:

- *Category I*: Eliminating Pathogens and Antitumor Efficacy: Jinlong Capsules (Grade II, strong recommendation)<sup>52</sup>; Huachansu Injection (Grade II, strong recommendation)<sup>53</sup>; Lanmanxi (Elemene) Emulsion/Injection (Grade II, strong recommendation)<sup>54</sup>; Fufang Kushen Injection (Grade II, strong recommendation)<sup>55</sup>; Huisheng Oral Liquid (Grade II, weak recommendation)<sup>56</sup>; Xiaoaiping Injection (Grade II, weak recommendation)<sup>57</sup>; Aidi Injection (Grade II, weak recommendation)<sup>58</sup>; Yadanzi Oil Emulsion (Grade II, weak recommendation).<sup>59</sup>
  - *Category II*: Strengthening Body Resistance: Kangai Injection (Grade II, strong recommendation)<sup>60</sup>; Shenqi Fuzheng Injection (Grade II, strong recommendation).<sup>61</sup>
  - *Category III*: Integrated Strengthening and Antitumor Efficacy: Huaier Granules (Grade II, strong recommendation)<sup>62</sup>; Yangzheng Xiaoji Capsules (Grade II, strong recommendation)<sup>63–67</sup>; Ganfule Capsules/Tablets (Grade II, strong recommendation)<sup>68</sup>; Kanglaite Injection (Grade II, strong recommendation)<sup>69</sup>; Cidan Capsules (Grade II, weak recommendation).<sup>70</sup>
- Prolonging survival:
- *Category I*: Eliminating Pathogens and Antitumor Efficacy: Fufang Kushen Injection (Grade II, strong recommendation),<sup>55</sup> Huachansu Injection (Grade II, strong recommendation),<sup>53</sup> Jinlong Capsules (Grade II, strong recommendation),<sup>52,71</sup> Aidi Injection (Grade II, weak recommendation),<sup>58</sup> Yadanzi Oil Emulsion (Grade II, weak recommendation),<sup>59</sup> Lanmanxi Emulsion/

Injection (Grade II, strong recommendation),<sup>54</sup> and Sodium Cantharidinate and Vitamin B6 Injection (Grade III, strong recommendation).<sup>72</sup>

- *Category II*: Integrated Strengthening and Antitumor Efficacy: Ganfule Capsules/Tablets (Grade II, strong recommendation),<sup>68</sup> Huaier Granules (Grade II, strong recommendation),<sup>62</sup> and Cidan Capsules (Grade II, weak recommendation).<sup>70</sup>
  - Improving QOL following TACE/ablation:
  - *Category I*: Eliminating Pathogens and Antitumor Efficacy: Fufang Kushen Injection (Grade II, strong recommendation),<sup>73</sup> Huachansu Injection (Grade II, strong recommendation),<sup>53</sup> Xiaoaiping Injection (Grade II, weak recommendation),<sup>57</sup> Huisheng Oral Liquid (Grade II, weak recommendation),<sup>56</sup> Aidi Injection (Grade II, weak recommendation),<sup>58</sup> and Yadanzi Oil Emulsion (Grade II, weak recommendation).<sup>59</sup>
  - *Category II*: Strengthening Body Resistance: Shenqi Fuzheng Injection (Grade II, strong recommendation).<sup>61</sup>
  - *Category III*: Integrated Strengthening and Antitumor Efficacy: Kanglaite Injection (Grade II, strong recommendation).<sup>69</sup>
- Immunomodulation:
- *Category I*: Eliminating Pathogens and Antitumor Efficacy: Jinlong Capsules (Grade II, strong recommendation) and Aidi Injection (Grade III, weak recommendation) can significantly elevate the levels of CD3<sup>+</sup>, CD4<sup>+</sup>, and CD4<sup>+</sup>/CD8<sup>+</sup> T-cell subpopulations.<sup>52,58</sup>
  - *Category II*: Strengthening Body Resistance: Kangai Injection (Grade II, strong recommendation),<sup>60</sup> Shenqi Fuzheng Injection (Grade II, strong recommendation),<sup>61</sup> and Yangzheng Xiaoji Capsules (Grade II, strong recommendation) can elevate the levels of CD3<sup>+</sup>, CD4<sup>+</sup>, CD4<sup>+</sup>/CD8<sup>+</sup>, NK cells, and the CD4<sup>+</sup>/CD8<sup>+</sup> ratio.<sup>63–67</sup>
  - *Category III*: Integrated Strengthening and Antitumor Efficacy: Huaier Granules (Grade II, strong recommendation) can increase the CD4<sup>+</sup>/CD8<sup>+</sup> T-cell ratio.<sup>62</sup>

### Ameliorating adverse reactions

#### *Category I*: Ameliorating Postoperative Adverse Reactions:

- Lanmanxi (Elemene) Injection can reduce the incidence of postoperative gastrointestinal reactions, fever, and bone marrow suppression (Evidence level: Grade II, strong recommendation).<sup>54</sup>
  - Fufang Kushen Injection can improve gastrointestinal reactions, leukopenia, and liver function abnormalities following TACE (Evidence level: Grade II, strong recommendation).<sup>55</sup>
  - Huachansu Injection (Grade II, strong recommendation),<sup>53</sup> Jinlong Capsules (Grade II, strong recommendation),<sup>52</sup> and Xiaoaiping Injection (Grade II, weak recommendation) can improve postoperative leukopenia and liver function abnormalities.<sup>57</sup>
  - Aidi Injection is effective in improving postoperative liver function abnormalities (Evidence level: Grade II, weak recommendation).<sup>58</sup>
  - Yadanzi Oil Emulsion can ameliorate postoperative leukopenia (Evidence level: Grade II, weak recommendation).<sup>59</sup>
- Category II*: Strengthening Body Resistance:
- Shenqi Fuzheng Injection can improve leukopenia and reduce the incidence of gastrointestinal reactions (Evidence level: Grade II, strong recommendation).<sup>61</sup>

### Ameliorating PES

The administration of CPMs, including Yangzheng Xiaoji Capsules (Grade III, weak recommendation),<sup>74,75</sup> Xuebijing Injection (Grade II, strong recommendation),<sup>76–79</sup> Qingkailing Injection (Grade III, weak recommendation),<sup>80</sup> Kangai Injection (Grade III,

weak recommendation),<sup>81,82</sup> Fufang Yexiazhu (Compound Phyllanthus) Granules (Grade III, weak recommendation),<sup>83</sup> Babaodan Capsules (Grade III, weak recommendation),<sup>84,85</sup> and Xihuang Capsules (Grade III, weak recommendation),<sup>86</sup> can significantly reduce the incidence of PES in patients with PLC.

### Integrated application of CPMs with radiotherapy

The clinical benefits of Chinese patent medicines combined with radiotherapy, including antitumor efficacy, survival, quality of life, immune function, and adverse reactions, are summarized in Supplementary Table 3.

#### Enhancing antitumor efficacy improving

*ORR*: Huaier Granules (Grade III, strong recommendation),<sup>87</sup> Jinlong Capsules (Grade II, strong recommendation),<sup>88</sup> Huachansu Injection/Tablets (Grade III, weak recommendation),<sup>89–91</sup> Fufang Banmao (Compound Cantharidin) Capsules (Grade II, strong recommendation),<sup>92</sup> Aidi Injection (Grade II, weak recommendation),<sup>93–95</sup> Fufang Kushen Injection (Grade II, weak recommendation),<sup>96,97</sup> and Fufang Danshen (Compound Salvia) Injection (Grade II, weak recommendation).<sup>98</sup>

*Improving disease remission rate*: Kanglaite Injection (Grade II, strong recommendation),<sup>99–101</sup> Norcantharidin (Grade II, strong recommendation),<sup>102</sup> and Kangai Injection (Grade III, weak recommendation).<sup>103</sup>

#### Prolonging survival

The combination of radiotherapy with medications such as Fufang Banmao Capsules (Grade II, strong recommendation),<sup>92</sup> Norcantharidin (Grade II, strong recommendation),<sup>102</sup> Sodium Cantharidinate and Vitamin B6 Injection (Grade III, weak recommendation),<sup>104</sup> Aidi Injection (Grade II, weak recommendation),<sup>94,95</sup> Huachansu Injection (Grade III, weak recommendation),<sup>89–91</sup> Huaier Granules (Grade III, strong recommendation),<sup>87</sup> Kanglaite Injection (Grade II, strong recommendation),<sup>99–101</sup> and Pianzaihuang (Grade III, strong recommendation) can increase survival rates or prolong OS.<sup>105</sup>

#### Improving QOL

The integrated application of Aidi Injection (Grade II, weak recommendation),<sup>94,95</sup> Sodium Cantharidinate and Vitamin B6 Injection (Grade III, weak recommendation),<sup>104</sup> Fufang Kushen Injection (Grade II, weak recommendation),<sup>96,97</sup> Kangai Injection (Grade III, weak recommendation),<sup>103</sup> and Kanglaite Injection (Grade II, strong recommendation) with radiotherapy can enhance the QOL for patients.<sup>99–101</sup>

#### Immunomodulation

Fufang Banmao Capsules (Grade II, strong recommendation),<sup>92</sup> Norcantharidin (Grade II, strong recommendation),<sup>102</sup> Aidi Injection (Grade II, weak recommendation),<sup>94,95</sup> Huachansu Tablets (Grade III, weak recommendation),<sup>89–91</sup> and Kanglaite Injection (Grade II, strong recommendation) can elevate the levels of CD3<sup>+</sup>, CD4<sup>+</sup>, CD8<sup>+</sup>, and the CD4<sup>+</sup>/CD8<sup>+</sup> T-cell ratio.<sup>99–101</sup>

#### Reducing recurrence and metastasis rates

Kangai Injection (Evidence level: Grade III, weak recommendation).<sup>103</sup>

#### Ameliorating adverse reactions

*Kangai Injection*: Ameliorates gastrointestinal reactions, leukope-

nia, and thrombocytopenia (Grade III, weak recommendation).<sup>103</sup>

*Kanglaite Injection and Pianzaihuang*: Ameliorate fatigue, gastrointestinal reactions, bone marrow suppression, and liver function abnormalities (Grade II/III, strong recommendation).<sup>99–101,105</sup>

*Fufang Banmao Capsules*: Reduces the incidence of bone marrow suppression (Grade II, strong recommendation).<sup>92</sup>

*Norcantharidin*: Can improve liver function abnormalities (Grade II, strong recommendation).<sup>102</sup>

### Integrated application of CPMs with chemotherapy

The effects of Chinese patent medicines combined with chemotherapy on antitumor efficacy, survival, quality of life, liver function, immune regulation, and adverse reactions are summarized in Supplementary Table 4.

#### Enhancing antitumor efficacy

*Improving ORR*: Kangai Injection (Grade II, weak recommendation),<sup>106–108</sup> Shenmai Injection (Grade III, strong recommendation),<sup>109</sup> Kanglaite Injection (Grade II, strong recommendation),<sup>110–115</sup> and Fufang Kushen Injection (Grade II, weak recommendation),<sup>116–122</sup> Improving disease remission rate: Cidan Capsules (Grade III, strong recommendation),<sup>123–125</sup> Aidi Injection (Grade II, strong recommendation),<sup>126–134</sup> and Dahuang Zhechong Pills (Grade III, weak recommendation).<sup>135–137</sup>

#### Prolonging survival

Dahuang Zhechong Pills (Grade III, weak recommendation) and Kanglaite Injection (Grade II, strong recommendation) are recommended to prolong OS.<sup>111–115,135–137</sup>

#### Improving QOL

The integrated application of the following medications with chemotherapy can enhance the QOL for patients: Huaier Granules (Grade II, strong recommendation),<sup>138,139</sup> Aidi Injection (Grade II, strong recommendation),<sup>126–134</sup> Kangai Injection (Grade II, weak recommendation),<sup>106–108</sup> Shenmai Injection (Grade III, strong recommendation),<sup>109,110</sup> Shenqi Fuzheng Injection (Grade III, weak recommendation),<sup>140,141</sup> Cidan Capsules (Grade III, strong recommendation),<sup>123–125</sup> Dahuang Zhechong Pills (Grade III, weak recommendation),<sup>135–137</sup> Huachansu Injection (Grade III, strong recommendation),<sup>142–144</sup> and Yadanzi Oil Soft Capsules (Grade III, weak recommendation).<sup>145</sup>

#### Ameliorating liver function abnormalities

Yadanzi Oil Soft Capsules (Grade III, weak recommendation),<sup>145</sup> Fufang Kushen Injection (Grade II, weak recommendation),<sup>116–122</sup> and Fufang Banmao Capsules (Grade III, strong recommendation) effectively improve liver function impairment during chemotherapy.<sup>146</sup>

#### Immunomodulation

The administration of Aidi Injection (Grade II, strong recommendation),<sup>126–134</sup> Kangai Injection (Grade II, weak recommendation),<sup>106–108</sup> Shenmai Injection (Grade III, strong recommendation),<sup>109,110</sup> Cidan Capsules (Grade III, strong recommendation),<sup>123–125</sup> Dahuang Zhechong Pills (Grade III, weak recommendation),<sup>135–137</sup> Fufang Kushen Injection (Grade II, weak recommendation),<sup>118,122</sup> Fufang Banmao Capsules (Grade III, strong recommendation),<sup>146</sup> Xiaozheng Yigan Tablets (Grade III, weak recommendation),<sup>147</sup> and Kanglaite Injection (Grade II, strong recommendation) can elevate the levels of CD3<sup>+</sup>, CD4<sup>+</sup>, CD8<sup>+</sup>, and the CD4<sup>+</sup>/CD8<sup>+</sup> T-cell ratio.<sup>111–115</sup>

### Ameliorating adverse reactions

Aidi Injection (Grade II, strong recommendation),<sup>126–134</sup> Kangai Injection (Grade II, weak recommendation),<sup>106–108</sup> Shenmai Injection (Grade III, strong recommendation),<sup>109,110</sup> Shenqi Fuzheng Injection (Grade III, weak recommendation),<sup>140,141</sup> Cidan Capsules (Grade III, strong recommendation),<sup>123–125</sup> Dahuang Zhechong Pills (Grade III, weak recommendation),<sup>135–137</sup> Fufang Kushen Injection (Grade II, weak recommendation),<sup>116–119,121,122</sup> Huachansu Injection (Grade III, strong recommendation),<sup>142–144</sup> and Kanglaite Injection (Grade II, strong recommendation) can effectively reduce the incidence of gastrointestinal reactions,<sup>111–115</sup> alopecia (hair loss), hepatic and renal dysfunction, and leukopenia. These medications also alleviate the severity and shorten the duration of such adverse reactions.

### Integrated application of CPMs with targeted/immunotherapy

The clinical roles of Chinese patent medicines in combination with targeted therapy and immunotherapy, including efficacy, survival, quality of life, and immune regulation, are summarized in Supplementary Table 5.

#### Enhancing antitumor efficacy

*Improving ORR:* Huaier Granules combined with sorafenib (Grade II, strong recommendation) can improve ORR and prolong survival.<sup>148</sup> Huachansu Capsules combined with sorafenib (Grade III, weak recommendation) may also enhance therapeutic efficacy and improve QOL.<sup>149</sup>

*Improving disease remission rate:* Huachansu Capsules/Tablets/Injection combined with sorafenib or lenvatinib (Grade II, strong recommendation),<sup>150,151</sup> Lanmanxi (Elemene) Injection combined with sorafenib (Grade II, weak recommendation).<sup>152,153</sup>

#### Prolonging survival

The combination of Lanmanxi Injection with sorafenib can prolong progression-free survival (Grade II, weak recommendation).<sup>152,153</sup> Huaier Granules combined with sorafenib (Grade II, strong recommendation) can improve ORR and prolong survival.<sup>148</sup> Huachansu Capsules combined with sorafenib (Grade III, weak recommendation) may also enhance therapeutic efficacy and improve QOL.<sup>149</sup>

#### Improving QOL

The following combinations can enhance patients' QOL: Huachansu Tablets with sorafenib or lenvatinib (Grade II, strong recommendation),<sup>150,151</sup> Jiedu Huoxue Formula combined with spleen polypeptide injection and apatinib may improve patients' QOL and immune function,<sup>154</sup> Shenqi Fuzheng Injection with sorafenib or apatinib (Grade II, strong recommendation),<sup>155–157</sup> and Huaier Granules combined with sorafenib (Grade II, strong recommendation) can improve ORR and prolong survival.<sup>148</sup> Huachansu Capsules combined with sorafenib (Grade III, weak recommendation) may also enhance therapeutic efficacy and improve QOL.<sup>149</sup>

#### Ameliorating liver function abnormalities

Shenqi Fuzheng Injection combined with sorafenib or apatinib effectively improves liver function impairment (Grade II, strong recommendation).<sup>155–157</sup>

#### Immunomodulation

Lanmanxi Injection combined with sorafenib (Grade II, weak recommendation),<sup>152,153</sup> and Shenqi Fuzheng Injection combined with sorafenib or apatinib (Grade II, strong recommendation),<sup>155–157</sup> can elevate CD4<sup>+</sup> and CD8<sup>+</sup> T-cell levels.

### Ameliorating adverse reactions

Lanmanxi Injection combined with sorafenib (Grade II, weak recommendation),<sup>152,153</sup> and Shenqi Fuzheng Injection combined with sorafenib or apatinib (Grade II, strong recommendation),<sup>155–157</sup> can alleviate adverse reactions induced by sorafenib, including gastrointestinal reactions, hypertension, and hand-foot syndrome.

### TCM treatment for PLC complications

The applications of Chinese patent medicines for managing complications of primary liver cancer, including ascites, fatigue, and pain, are summarized in Supplementary Table 6.

#### Ameliorating malignant ascites

Intraperitoneal perfusion of cisplatin combined with Aidi Injection (Grade II, strong recommendation),<sup>158</sup> Kangai Injection (Grade II, weak recommendation),<sup>158</sup> Lanmanxi (Grade II, weak recommendation),<sup>158</sup> or Fufang Kushen Injection (Grade II, weak recommendation) can effectively ameliorate malignant ascites.<sup>158</sup>

#### Ameliorating cancer-related fatigue

Kangai Injection can alleviate cancer-related fatigue following chemotherapy, improve QOL, and reduce the incidence of post-chemotherapy adverse reactions such as leukopenia, alopecia, and constipation (Grade III, weak recommendation).<sup>159</sup>

#### Ameliorating cancer-related pain

The combination of Huachansu Injection with morphine sustained-release tablets for cancer-related pain can reduce morphine dosage and enhance the QOL for patients (Grade III, weak recommendation).<sup>160</sup>

### External TCM therapies based on pattern differentiation

#### Overview

External TCM therapies, guided by fundamental TCM theories, are methods applied to the body surface or performed externally. These therapies primarily function through pharmacological, thermal, and mechanical actions. By acting directly on the skin or the site of limb lesions, they regulate Qi and blood, dredge meridians, penetrate the striae and interstices (chouli), strengthen body resistance and eliminate pathogens, warm meridians to dissipate cold, resolve swelling and nodules, and unblock collaterals to relieve pain. These methods constitute an essential component of TCM.<sup>161</sup> Commonly used external TCM therapies include massage, cupping, TCM enema, acupoint application, acupuncture, and moxibustion (filiform needle acupuncture, electroacupuncture, and moxibustion), and auricular point pressing.

#### Ameliorating postoperative adverse reactions

External TCM therapies can alleviate symptoms such as abdominal distension, intestinal obstruction, nausea, vomiting, hiccup, and sleep disorders following surgical resection of PLC.

*Gastrointestinal dysfunction:* For patients with abdominal distension or intestinal obstruction, recommended interventions include:

- TCM enema (Dahuang Fuzi Xixin Tang) (Grade III, strong recommendation).<sup>162</sup>
- Colonic dialysis followed by TCM enema (Decoction of Dahuang, Houpo, Zhishi, and Mangxiao in a 4:8:4:3 ratio) (Grade III, strong recommendation).<sup>163</sup>
- Acupoint application at Zusanli (ST36) using Houpo powder combined with auricular point pressing (points: large intestine,

small intestine, stomach, spleen, sympathetic, etc.) (Grade II, strong recommendation).<sup>164–167</sup> These methods improve abdominal distension and promote the recovery of flatus, defecation, and bowel sounds. *Nausea and vomiting*: Acupoint application using Wuzhuyu powder mixed with ginger juice at bilateral Neiguan (PC6), Zusanli (ST36), and Zhongwan (CV12) (Grade III, strong recommendation).<sup>168</sup>

*Intractable hiccup*: Electroacupuncture at Cervical Jiaji points (Grade III, strong recommendation).<sup>169</sup>

*Sleep disorders*: Auricular point pressing (points: Shenmen, endocrine, liver, kidney, etc.) (Grade III, strong recommendation).<sup>170,171</sup>

*Liver depression and spleen deficiency pattern*: Auricular point pressing (points: Shenmen, subcortex, heart, sympathetic, endocrine, liver, spleen, etc.) (Grade III, strong recommendation).<sup>171</sup>

### Ameliorating post-chemotherapy anorexia

Transcutaneous electrical acupoint stimulation at Hegu (LI4), Neiguan (PC6), and Zusanli (ST36) combined with palonosetron can improve anorexia following chemotherapy for PLC (Grade II, strong recommendation).<sup>172</sup>

### Ameliorating ascites

External application of TCM (applied to the body surface projection of the deepest ascitic area; commonly used herbs: Mangxiao, Dafupi, Zhuling, Fuling, etc.) combined with conventional Western medicine can reduce ascitic fluid volume and ameliorate symptoms such as abdominal distension, poor appetite, and lower extremity edema (Grade III, strong recommendation).<sup>173–175</sup>

### Ameliorating cancer-related fatigue

Moxibustion at Guanyuan (CV4), Zusanli (ST36), and Shenque (CV8) can alleviate cancer-related fatigue in patients with PLC (Grade III, strong recommendation).<sup>176,177</sup>

### Relieving cancer-related pain

Recommended external therapies for pain relief include:

- Acupoint application (points: Riyue [GB24], Qimen [LR14], Zhangmen [LR13], Shenque [CV8], Ganshu [BL18], Danshu [BL19], etc.; commonly used herbs: Ruxiang, Moyao, Jianghuang, Chuanxiong, Dingxiang, etc.) (Grade II, strong recommendation).<sup>178–184</sup>
- Acupuncture (points: Zusanli [ST36], Neiguan [PC6], Hegu [LI4], Sanyinjiao [SP6], etc.) (Grade III, strong recommendation).<sup>185</sup>
- Heat-sensitive moxibustion (points: Right Zhangmen [LR13], Right Riyue [GB24], Bilateral Xuehai [SP10], Bilateral Sanyinjiao [SP6], and Bilateral Taichong [LR3]) (Grade III, strong recommendation).<sup>186</sup>
- Auricular point pressing (points: abdomen, liver, spleen, stomach, sympathetic, Shenmen, heart, etc.) (Grade III, strong recommendation).<sup>187</sup>

## Health management and nursing care

### Emotional regulation (*Diaoshe Qingzhi*)

Patients with liver cancer often experience negative emotions such as fear, anxiety, and depression, which significantly impact treatment and recovery.<sup>188,189</sup> Psychological interventions can guide patients to cope positively with the disease and its treatment. Medical personnel may employ TCM emotional induction therapy (*Qingzhi Shudao*) to regulate patient emotions. This includes various intervention methods such as:

- Explanation and reassurance (*Shiyi Jiehuo*).
- Distraction and character transformation (*Yiqing Yixing*).
- Emotional counter-balancing (*Qingzhi Xiangsheng*).

These methods aim to harmonize Yin and Yang, ensure the smooth flow of Qi and blood, and promote a pleasant mental state.<sup>190</sup> Support from professional psychologists should be sought when necessary.

### Dietary nursing (*Yinshi Tiaohu*)

Patients with liver cancer should follow the dietary principles of “high protein, high vitamins, and a balanced diet”.<sup>191</sup>

*Nutritional intake*: Consume appropriate amounts of high-protein foods, such as fish, shrimp, eggs, and milk, along with fresh vegetables and fruits to maintain regular bowel movements.

*Dietary restrictions*: Strictly abstain from alcohol, avoid high-fat diets, and refrain from consuming hard or irritating foods.

*Complication-specific care*: Patients prone to postoperative ascites must strictly control salt intake, prioritizing a low-sodium diet.

*Decompensated cirrhosis*: For patients in the decompensated stage of liver cirrhosis, appropriate late-night snacks should be provided.

### Rehabilitation and rest (*Kangfu Xiuyang*)

Patients may engage in appropriate exercise based on their condition, prioritizing aerobic activities.<sup>192</sup>

*Recommended activities*: Slow walking, fitness Qigong, Tai Chi, yoga, and square dancing.

*Exercise planning*: Specific exercise plans should be tailored to the patient’s age, gender, treatment history, and physical status.

*Implementation*: Training should be progressive and adjusted promptly according to the patient’s specific circumstances.<sup>193</sup>

Appropriate exercise helps improve the QOL and promotes disease recovery.

## Monitoring and follow-up

In accordance with the TCM theory of Preventive Treatment of Disease (*Zhi Wei Bing*), the prevention and control of PLC prioritize “preventing disease before it occurs, preventing deterioration after it occurs, and preventing recurrence after recovery”. Following the tertiary prevention principles proposed in the Consensus on Tertiary Prevention of Primary Liver Cancer (2022 Edition),<sup>194</sup> monitoring and follow-up for patients after radical treatment should be conducted based on recurrence risk stratification. This involves managing etiology-related diseases and implementing anti-recurrence therapies to reduce recurrence rates, improve early diagnosis of recurrent PLC, and enhance long-term prognosis.

Patients with liver cancer should undergo regular monitoring. The following measures can be employed to monitor intrahepatic recurrence and extrahepatic metastasis:

*Serological markers*: Combined testing of serum AFP, AFP-L3, and/or des-gamma-carboxy prothrombin.<sup>194</sup>

*Imaging modalities*: Abdominal ultrasound; Multiparametric MRI; Dynamic contrast-enhanced CT; If necessary, PET-CT and/or bone scintigraphy (bone scan) can be performed.<sup>194</sup>

## Prevention

The following preventive measures are established with reference to the Expert Consensus on Primary Prevention of Liver Cancer in China (2018) and the Consensus on Secondary Prevention of Primary Liver Cancer (2021 Edition).<sup>195,196</sup>

### Primary prevention

Primary prevention involves measures to prevent the initial harm of risk factors that can lead to HCC in the general population. The target population is the general public. Specific measures include:

- *Hepatitis B vaccination*: Implementation of prophylactic vaccination programs, including specific immunization schedules for newborns and children of mothers with different HBV infection statuses.
- *Antiviral therapy*: Treatment for patients with chronic hepatitis B and C.
- *Environmental safety*: Prevention and avoidance of exposure to aflatoxin and cyanobacterial toxins.
- *Lifestyle modification*: Altering lifestyles associated with high carcinogenic risks.

### Secondary prevention

Secondary prevention focuses on populations with chronic liver disease, aiming to control related etiologies and risk factors while performing screening and monitoring based on risk stratification to reduce or delay the occurrence of HCC. The target population is individuals with chronic liver disease. Specific measures include:

- *Etiological treatment*: Antiviral therapy for HBV/HCV and treatment for other underlying causes of liver disease.
- *Anti-fibrotic therapy*: Treatments aimed at reducing or reversing hepatic fibrosis.
- *Risk factor control*: Management of relevant health and environmental risk factors.
- *Screening and monitoring*: Implementation of protocols for the early detection and monitoring of HCC development.

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