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MINI-REVIEW

Renoprotective effect of traditional herbal medicine of ancient Chinese origin: A mini-review

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Abstract

Prevention of chronic kidney disease (CKD) progression represents a critical challenge in global health care. However, the effectiveness of current pharmacologic interventions remains limited, requiring further therapeutic advancements. Traditional herbal medicine (THM) has been used worldwide in the treatment of CKD, but its effect remains uncertain. This review aims to evaluate the efficacy of THM in managing CKD and to identify appropriate methods for assessing its therapeutic effect. A literature search of six databases was conducted. The inclusion criteria comprised (i) ≥100 sample sizes, including retrospective studies, reviews, randomized controlled trials (RCTs), quasi-RCTs, crossover trials, and meta-analyses; (ii) CKD patients as the target; (iii) the use of oral THM as interventions; and (iv) reported primary and secondary outcomes. There were 18 RCTs with 3452 participants, 12 systematic reviews, 4 meta-analyses, and 4 retrospective studies. Although THM improved glomerular filtration rate, its therapeutic effect was uncertain due to major limitations, such as small sample sizes and short follow-up periods. THM formulas are prescribed based on THM diagnosis in a timely manner, meaning that patients sharing the same Western medical diagnosis may receive different formulas, and that prescriptions for a single patient may change during treatment. This approach may be a key reason for the small sample sizes and short follow-up periods of most THM studies against CKD. The use of quality-assured and ready-to-use Kampo extracts in a timely manner may be a promising method for the clinical application of THM in CKD treatment and the evaluation of its actual therapeutic effects.

Keywords: Traditional herbal medicine; Kampo extracts; Glomerular filtration rate; Chronic kidney disease

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1. Introduction

Preservation of renal function represents a critical challenge in global healthcare: 1.2 million (95% uncertainty interval [UI] 1.2–1.3) people died from chronic kidney disease (CKD) globally in 2017, and the global all-age mortality rate of CKD increased 41.5% (95% UI 35.2–46.5) between 1990 and 2017.[1] CKD is not only a leading cause of end-stage renal disease (ESRD) but also associated with increased mortality and cardiovascular disease.[2] It is defined as abnormalities of kidney structure or function for a minimum of 3 months (decreased glomerular filtration rate [GFR] < 60 mL/min/1.73 m^2), or having at least one marker of kidney damage, including albuminuria (≥30 mg/gCr),

urine sediment abnormalities, persistent hematuria, electrolyte and other abnormalities due to tubular disorders, abnormalities detected by histology, structural abnormalities detected by imaging, and a history of kidney transplantation.[2] Although current pharmacologic interventions, including sodium-glucose cotransporter 2 inhibitors, mineralocorticoid receptor antagonists, and renin–angiotensin system inhibitors, are commonly used to delay CKD progression, their effectiveness remains limited, requiring further therapeutic advancements.

Traditional herbal medicine (THM) has been used worldwide in the treatment of CKD. There are several randomized controlled trials (RCTs) of traditional Chinese medicine (TCM) against CKD. However, its therapeutic effect remains uncertain due to major limitations, such as small sample sizes and short follow-up periods.[3-5] THM, including Kampo formulas, is prescribed based not only on patients' complaints, signs, and symptoms but also on physical examinations, including abdominal, tongue, and pulse inspections. This means that patients sharing the same Western medical diagnosis (e.g., CKD due to diabetic nephropathy or systemic lupus erythematosus) may receive different formulas, and that prescriptions for a single patient may change during treatment based on traditional medical diagnosis (e.g., initially apply a formula to remove dampness, then change to another formula for invigorating qi). Hence, it is unusual to prescribe a single THM formula over a long period to all patients with CKD. It is therefore important to apply the correct formula to each patient in a timely fashion to determine the effectiveness of long-term administration of THM against CKD. This approach may be a key reason for the small sample sizes and short follow-up periods of most clinical studies of THM against CKD. This review aims to discuss recent reports on THM of ancient Chinese origin, against CKD, with a future perspective for the renoprotective effect of Kampo extract administration.

2. Methodology

Six databases (PubMed, the Cochrane Central Register, J-STAGE [https://www.jstage.jst.go.jp/browse/-char/ja], Web of Science, Evidence Reports of Kampo Treatment database [http://www.jsom.or.jp/medical/ebm/ere/index.html],[6] and the Japan Kampo Manufacturers Association database) were searched from inception to December 21, 2025. Missing studies were supplemented by manual retrieval of relevant reviews and studies. The search terms (subject headings, free terms, keywords, etc.) used included "chronic kidney disease, CKD," "chronic renal failure," "glomerular filtration rate, GFR," "creatinine," "cystatin C," "creatinine clearance," "eGFR slope," "proteinuria," "albuminuria," "urinary protein to creatinine ratio, UPCR," "urinary albumin to creatinine ratio, UACR," "traditional herbal medicine," "Kampo," "traditional Chinese medicine," and "randomized controlled trial, RCT." Different databases were searched using different strategies by combining various search terms.

The inclusion criteria comprised:

(i) Types of studies: Sample size of more than 100, including RCTs, quasi-RCTs, and crossover trials, as well as retrospective studies, reviews, and meta-analyses
(ii) Types of patients: CKD patients
(iii) Types of interventions: THM, orally combined with Western medicine in the treatment group versus Western medicine only in the control group, with unlimited courses of treatment.
(iv) Types of outcomes: Primary outcomes (e.g., serum creatinine, blood urea nitrogen, and cystatin C [cys]) and secondary outcomes (e.g., 24 h urine protein, urinary protein-to-creatinine ratio [UPCR], and urinary albumin-to-creatinine ratio).

The exclusion criteria comprised:

(i) Types of studies: Ongoing clinical trials, pre-clinical studies (cell and animal experiments), and non-comparative or uncontrolled clinical reports (e.g., self-controlled studies, case reports, etc.).
(ii) Types of patients: Acute kidney injury patients and CKD patients with ongoing renal replacement therapies.
(iii) Types of interventions: Non-oral traditional medicine, including acupuncture, intravenous injection, plaster, and foot bath, and the use of THM in the control group.
(iv) Types of outcomes: No primary and secondary outcomes.
(v) Others: Incomplete data and repeated publication.

3. Results

A total of 4742 records were identified, of which 4737 were retrieved through initial database searches. The remaining five studies were identified through the reference list screening of the 4742 records and subsequent database searches. After removal of duplicate records and exclusion of studies based on the exclusion criteria, 41 records remained for full-text review. There were 18 RCTs involving 3452 participants, with sample sizes ranging from 118 to 1,470. In addition, there were 12 systematic reviews, 4 meta-analyses, 4 retrospective studies, and 3 prospective studies.

4. Pathophysiology of CKD and limitations of clinical studies using THM

Pathologically, initial global glomerular sclerosis, or obstruction by inflammation or abnormal deposits, leads to the reduction of blood flow and glomerular filtration, and the tubules supplied by the efferent arteriole undergo ischemia and eventually atrophy with adjacent interstitial fibrosis.[7] There is also primary tubulointerstitial disease, which leads to tubular atrophy and interstitial fibrosis. Disease affecting glomeruli characteristically exhibits one or more patterns of injury, including histological signs of inflammation such as hypercellularity, infiltrating leukocytes, fibrinoid necrosis, segmental sclerosis, and glomerular basement membrane remodeling. Interstitial inflammation, tubular epithelial necrosis, and vascular sclerosis, hyalinosis, inflammation, necrosis, or thrombosis are characteristics of interstitial, tubular, and vascular diseases, respectively.[7] Glomerular diseases occur not only as diseases that primarily target the kidneys but also as components of systemic diseases, including systemic lupus erythematosus, diabetes mellitus, amyloidosis, monoclonal immunoglobulin deposition disease, hypertension, and systemic vasculitides such as anti-neutrophil cytoplasmic antibody vasculitis, immunoglobulin A vasculitis, and cryoglobulinemic vasculitis.[7] Nephrological treatments are mainly evaluated by the change in GFR and proteinuria, as decreased GFR and proteinuria are closely related to the development of advanced-stage CKD, which leads to further decline in GFR.[2]

Pathophysiology of CKD in traditional medicine is composed of qi deficiency, weakness of kidney[traditional medicine module 1 (TM1)], blood[TM1] deficiency, and abnormal blood[TM1] circulation, leading to dampness heat, blood[TM1] stasis, water stagnation, and turbid toxin.[4] Therefore, THM is thought to exert therapeutic effects against CKD through invigorating qi, tonifying kidney[TM1] and blood[TM1], promoting blood[TM1] circulation, and removing stasis, heat, dampness, turbidity, and edema. These effects are multitargeted and multifunctional.

THM exerts anti-inflammatory, antifibrotic, antioxidant, antiapoptotic, and immunomodulatory effects; the mechanisms of these renoprotective effects are recently reviewed in detail.[4] For example, transforming growth factor-β/Smad and Wnt/β-catenin signaling pathways are two antifibrotic mechanisms that have been validated by several TCM studies.[4] In addition to inhibiting the activation of advanced glycation end products, the anti-inflammatory effect of THM is also manifested in the inhibition of reactive oxygen species–extracellular signal-regulated kinase 1/2–nuclear factor kappa B-mediated NOD-, LRR-, and pyrin domain-containing protein 3 inflammasomes.[4]

THM is applied as formulas, which consist of several crude drugs. *Shanghanlun* and *Jinguiyaolue*, medical books considered to have been written by Zhang Zhongjing in the later Han dynasty, discuss the treatment of acute febrile illness and various chronic diseases, respectively.[8] These ancient medical books present precise prescriptions of hundreds of formulas and provide helpful suggestions to utilize each of them. There are also thousands of new formulas created after the Song and Yuan dynasties, and even now, new formulas are being introduced. New Kampo formulas have also emerged in Japan since THM was officially imported from China through the Korean peninsula in 552 AD and evolved for about 1500 years.[9] These formulas are prescribed to CKD patients under traditional medical diagnosis.[10,11]

Subsequent sections focus on the renoprotective effects of individual crude drugs and individual formulas, as well as on THM as a broad therapeutic category with pharmacological heterogeneity. Finally, this review proposes the use of Kampo extracts as an approach for the proper administration of THM in the treatment of CKD.

5. Renoprotective effects of individual crude drugs

Numerous reports have detailed the renoprotective effects of individual crude drugs, as extensively reviewed in recent literature.[3-5] Among these, astragalus root, which invigorates qi, is one of the most studied crude drugs for CKD treatment.[4] Multiple clinical studies have reported the renoprotective effects of astragalus root.[12-14] Astragalus root is thought to exert its effect through preserving the glomerular filtration barrier, enhancing tight junctions and glycocalyx, increasing nitric oxide (NO) production through the activation of endothelial NO synthase, scavenging reactive oxygen species, and modulating mitochondrial function.[12,15] Clinical studies have shown that astragalus root may improve proteinuria,[3-5] but others also reported that astragalus root improved GFR without affecting proteinuria.[14] *Rhei Radix et Rhizoma* for eliminating heat and dampness[16,17] and *Salviae Miltiorrhizae Radix et Rhizoma* (*Danshen*) for promoting blood circulation and removing stasis[16,18] are examples of crude drugs that are reported to have renoprotective effects.[3-5]

6. Renoprotective effects of individual formulas

There are numerous studies concerning the renoprotective effects of THM formulas, and these are described in

detail in recent reviews.[3-5] *Shenqi* particle,[19] *Tangshen* formula,[20,21] *Jinshuibao*,[22] *Shenqi Yanshen* granule,[23] *Tongxinluo* capsule,[24] *Huangkui* capsule,[25,26] *Bupi Yishen* formula,[27] Niaoduqing particles,[28] and *saireito*[29] have been shown to exert renoprotective effects (e.g., improve GFR and reduce proteinuria) in clinical trials, but other formulas improve GFR without affecting proteinuria.[28] The longest intervention period for these clinical trials was 12 months,[19,25,27] which may indicate the difficulty of maintaining a single formula throughout the course of clinical trials involving THM. Table 1 presents representative clinical trials of THM formulas for CKD. Long-term RCTs with hard endpoints are required to evaluate the effects of THM in CKD management.

7. Renoprotective effects of THM as a broad therapeutic category with pharmacological heterogeneity

There are reports indicating that THM, as a broad therapeutic category, may provide renoprotective effects. A large-scale propensity score-matched analysis including 8195 pairs of newly diagnosed CKD patients utilizing the Taiwan National Health Insurance Research Database showed that prescription of THM, for a median of 22 days (interquartile range 7–62 days), resulted in 60% risk reduction of 6-year cumulative ESRD incidence compared with non-users.[31] The patients in that study consisted of stage 3–5 newly diagnosed CKD patients with a mean age of 54 years, 39% female, including 24% with diabetes mellitus, 33% with hypertension, and 6% with cardiovascular disease. More detailed analysis revealed that the use of harmonizing, wind-dampness-dispelling, blood-regulating, qi-regulating, and summer-heat-clearing formulas—comprising a total of 163 different formulas—was associated with a lower incidence of ESRD. However, the use of dampness-dispelling and purgative formulas, which included 78 different formulas, was associated with an increased ESRD risk. This increased ESRD risk may be due to the use of strong formulas that may lead to dehydration (e.g., *Shu Zao Yin Zi*, or *sosakuinshi*), but the precise dosage and treatment duration were not clearly defined.

Recently, a retrospective study evaluated the effectiveness of long-term administration of Kampo formula extracts on renal function.[32] Using a propensity score-matched analysis, 148 pairs of Kampo extract users and non-users with similar pre-treatment GFR slope, household income, educational level, and smoking status (64% female, mean ages 68.8 and 68.9 years, mean estimated GFR [eGFR] 68.3 and 68.2 mL/min/1.73 m^2, UPCR 0.12 ± 0.15 and 0.12 ± 0.18 g/gCr, respectively), were analyzed. The cohort included 40% CKD patients and 26% with diabetes mellitus. The analysis demonstrated that Kampo use may attenuate the decline in renal function. The mean difference in eGFR slope between Kampo users and non-users was 1.07 mL/min/1.73 m^2/year (95% confidence interval [CI] 0.68–1.46) over a mean follow-up of 8.7 ± 2.1 years in the overall cohort, and 1.48 mL/min/1.73 m^2/year (95% CI 0.75–2.22) over 9.4 ± 2.1 years among patients with CKD. These results meet the surrogate endpoint of

Table 1. Representative clinical trials of traditional herbal medicine for CKD

Intervention	Disease	*N*	Trial period (months)	Primary outcome	Outcome	Reference
Shenqi particle vs. prednisone/ cyclophosphamide	Idiopathic membranous nephropathy	190	12	CR+PR	46/63 (73.0%) vs. 54/69 (78.3%) (p=0.5)	19
Tangshen formula vs. placebo	Type 2 diabetic kidney disease	180	6	UAER+24 h UP	ΔUAER: −19.5 vs. −7.0 μg/min (p=0.7); Δ24 h UP: −0.2 vs. 0.4 g (p<0.05)	21
Huangkui capsule (*Abelmoschus manihot*) vs. losartan	Immunoglobulin A nephropathy	1,470	12	Pre vs. post 24 h UP	ΔUP: −230 vs. −253 mg (p=0.6)	25
Bupi Yishen formulation vs. Losartan	Non-diabetic CKD stage 4	567	12	eGFR slope	−2.3 vs. −4.5 mL/min/1.73 m^2/year (p<0.05)	27
Niaoduqing particles (UCG) vs. placebo	CKD stage 3b–4	300	6	Pre vs. post sCr and eGFR	ΔsCr: 1.1 vs. 11.7 μmol/L (p<0.01); ΔeGFR: −0.2 vs. −2.2 mL/min/1.73 m^2 (p<0.05)	28
Chinese herbal formulation granules vs. placebo	CKD stage 3	343	6	24 h UP+sCr+eGFR	24-h UP: 0.97±1.14 vs. 0.97±1.25 g/day (p<0.05); sCr: 130.8±32.6 vs. 149.1±41.3 μmol/L (p<0.05); eGFR: 55.74±50.82 vs. 44.46±12.60 mL/min/1.73 m^2 (p<0.05)	30

Abbreviations: CKD: Chronic kidney disease; CR: Complete remission; eGFR: Estimated glomerular filtration rate; PR: Partial remission; sCr: Serum creatinine; UAER: Urinary albumin excretion rate; UCG: Uremic clearance granules; UP: Urinary protein.

eGFR slope reduction of 0.5–1.0 mL/min/1.73 m^2/year, as proposed by an international workshop hosted by the National Kidney Foundation.[33] In that study, 107 Kampo extracts out of 148 Kampo extract prescription formulas approved by the Japanese insurance system (http://mpdb.nibiohn.go.jp/stork/) were administered.[32] Analysis of total Kampo extract prescriptions revealed six therapeutic categories—blood[TM1]-tonifying, kidney[TM1]-tonifying, yang-tonifying, qi- and yin-tonifying, qi-regulating, and wind-dampness-dispelling formulas—were more frequently prescribed to patients with preserved eGFR, although these differences were not statistically significant. Kampo formulas containing astragalus root were administered to 75% of Kampo users, with no significant difference in use between patients with preserved versus decreased eGFR. While Kampo users with preserved eGFR tended to have a higher intake of astragalus root compared to those with decreased eGFR (3,297 ± 2,266 g vs. 2,430 ± 2,001 g, respectively), this difference was not statistically significant. No individual Kampo formula or category was significantly associated with preservation or decline of eGFR. Furthermore, variations between eGFR calculated from serum creatinine (eGFRcr) and cystatin C (eGFRcys) were not significantly different between Kampo users and non-users at the study endpoint, suggesting that improvements in eGFRcr among Kampo users may reflect true renoprotection rather than compounding factors such as muscle mass or hemodynamic changes.

These findings indicate that Kampo extracts, administered as a broad therapeutic category with pharmacological heterogeneity, may exert renoprotective effects. However, despite adjustment for socioeconomic factors, there is a risk of healthy user bias, as patients who maintain long-term Kampo therapy may inherently represent a healthier or more adherent subpopulation, potentially contributing to preserved renal function.[32] Importantly, causal inferences cannot be drawn due to the observational and non-randomized nature of the study.

8. Future perspective on the renoprotective effects of THM: Use of Kampo extract granules as ready-to-use, quality-assured pharmaceuticals

To determine the efficacy of THM against CKD, treatment must be tailored to each patient's individual syndrome or pattern, with formulas adjusted accordingly as the patient's condition changes. Furthermore, long-term administration is essential, given that CKD is a chronic disorder that progresses over decades. Therefore, THM treatment must be easy and convenient for patients to adhere to.

Kampo extract granules are quality-assured pharmaceuticals listed in the Japanese pharmacopoeia (http://mpdb.nibiohn.go.jp/stork/),[34] approved and covered by the Japanese insurance system, and are orally administered. Utilizing ready-to-use Kampo extracts may facilitate the timely selection of the best-matched formula for each patient. Although Kampo medicine originated from ancient Chinese medicine, it has developed distinctly within Japan, where accumulated clinical experience has shaped its unique approach to understanding body responses and symptom management.[9,10,35]

In the Japanese medical system, Kampo extracts can be prescribed by Western-trained medical doctors without further certification or additional training in traditional medicine. It is reported that 86.7% of Japanese medical doctors are current users of Kampo formulas, with only 3.8% having no experience in their use.[36] Despite widespread clinical use, rigorous clinical studies evaluating Kampo formulas, especially for CKD, remain lacking, and no RCTs using Japanese Kampo formulas in CKD have been reported.

The *Evidence-based clinical practice guideline for CKD 2023*, published by the Japanese Society of Nephrology, highlights coffee intake as potentially suppressing the progression of CKD due to its antioxidants and anti-inflammatory substances, such as caffeine.[37] Kampo extracts similarly possess strong radical scavenging activity,[38,39] with reported antioxidant, anti-inflammatory, and antifibrotic effects across various diseases.[40,41]

Although some studies investigating THM in CKD failed to show significant improvements in proteinuria or albuminuria compared to controls, these negative results may be attributable to small sample sizes or relatively low baseline levels of proteinuria, limiting the ability to detect protective effects. Notably, 48-week administration of astragalus root has been reported to significantly improve eGFR slope without improving albuminuria in an RCT involving 118 diabetic patients with CKD stages G2–G3.[14] Similarly, *Niaoduqing* particles improved eGFR without improving proteinuria compared with controls.[28]. These findings suggest that the renoprotective effects of THM may occur independently of improvements in proteinuria.

9. Conclusion

Recent retrospective studies indicate that long-term administration of THM may slow eGFR decline in patients with CKD. The use of Kampo extracts represents a promising approach to rigorously evaluate the therapeutic potential of THM in CKD management.

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