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Introduction

Liver diseases ranging from drug-induced hepatotoxicity and alcoholic or **non-alcoholic fatty liver disease (NAFLD)** to **viral hepatitis**, cholestatic conditions, and cirrhosis remain **a major global health burden**.^[1] In Ayurveda, the liver diseases are referred as 'Kāmala' which literary mean "Kāmam Lunāti Iti Kāmālati". Here Kāmam means Icchā or desires, and Lāti means Runaddhi or Bādhanti or to diminish.^[2] Conventional therapy often focuses on supportive care; antifibrotic and regenerative options are limited. In this context, traditional systems of medicine such as Ayurveda offer multi-herb formulations with long-standing empirical use in jaundice (Kāmala), intermittent fevers, toxin exposure, and metabolic derangements.^[3] Paṭolakaṭurohiṇyādi Kaṣāya (PKK) is a classical polyherbal formulation indicated in Aṣṭāṅgahṛdaya under the chapter of Śodhanādi gaṇa saṅgraha, indicated in Kapha–Pitta vikāra, Kuṣṭha, Jvara, Viṣa, Chardi, Arochaka, Kāmalahara.^[4] Given rising interest in integrative medicine, systematic scientific evaluation of PKK is needed.

The rationale for this review is to collate and critically analyze current evidence both from modern pharmacology of constituent herbs and from preclinical/clinical studies involving PKK to assess whether classical references can translate into evidence-based hepatoprotection, and to identify gaps and future research priorities.

Classical Composition, Ayurvedic Rationale, and Challenges in Modern Standardization

PKK is described in the classical Ayurvedic text Aṣṭāṅgahṛdaya under Śodhanādi gaṇa saṅgraha chapter, and is traditionally indicated for disorders such as Kāmala, Kapha–Pitta conditions, Viṣa (poisonings), Kuṣṭha (skin diseases), Jvara (fevers), Aruci (anorexia), digestive disturbances, and metabolic derangements. The decoction is prepared by boiling a formulation of herbs, reducing the volume, filtering, and administering with warm water. Its constituent of the formulation^[5,6] are as mentioned in Table 1.

Table 1: Composition of Paṭolakaṭurohiṇyādi Kaṣāya

Name	Scientific Name	Family	Part Used	Rasa	Guṇa	Vīrya	Vipāka	Karma
Paṭola ^[7]	<i>Trichosanthes dioica</i> Roxb.	Cucurbitaceae	Phala	Tikta	Laghu, Rūkṣa	Uṣṇa	Kaṭu	Kapha–Pitta śāmaka, Dīpana

Kaṭurohīnī (Kuṭkī)[8]	<i>Picrorhiza kurroa</i> Royle ex Benth.	Plantaginaceae	Mūla	Tikta, Kaṣāya	Laghu, Rūkṣa	Śīta	Kaṭu	Pittahara, Rechana, Yakṛt-uttejaka
Madhusravā (Mūrvā)[9]	<i>Marsdenia tenacissima</i> R. Br	Apocynaceae	Mūla	Tikta	Laghu	Uṣṇa	Kaṭu	Tridoṣaghna
Guḍūcī[10]	<i>Tinospora cordifolia</i> (Willd.) Miers	Menispermaceae	Kāṇḍa	Tikta, Kaṣāya	Laghu, Snigdha	Uṣṇa	Madhura	Tridoṣahara, Rasāyana
Pāṭhā[11]	<i>Cissampelos pareira</i> L.	Menispermaceae	Mūla	Tikta	Laghu	Uṣṇa	Kaṭu	Kapha-Pitta śāmaka
Candana[12]	<i>Santalum album</i> L.	Santalaceae	Hṛḍaya	Tikta, Madhura	Laghu, Rūkṣa	Śīta	Kaṭu	Pittāśāmana

Mode of Action based on Rasapañcaka

Paṭolakaṭurohīnyādi Kaṣāya predominantly exhibits Tikta and **Kaṣāya rasa, Laghu–Rūkṣa guṇa, Uṣṇa vīrya, and Kaṭu vipāka**, which collectively contribute to Kapha–Pitta śāmaka, Dīpana–Pācana, Rakta śodhana, and Viśaghna actions. Paṭola, Kaṭukī, Candana, and Pāṭhā primarily pacify Kapha and Pitta, while Guḍūcī and Mūrvā exhibit Tridoṣahara properties, with Guḍūcī acting as a key Pittaśāmaka and Rasāyana, especially relevant as Pitta is the principal Doṣa involved in Kāmala. The predominance of Tikta rasa supports Pittaja vikāra śāmaka, bile regulation, and metabolic correction, whereas Kaṣāya rasa aids in tissue stabilization and anti-inflammatory effects. As the liver is considered the Mūlsthāna of Raktavaha srotasa and shares an Āśraya–Āśrayī bhāva relationship with Rakta and Pitta, drugs that pacify Rakta and Pitta exert a direct therapeutic effect on hepatic pathology. Thus, the collective Rasapañcaka attributes of PKK provide a sound Ayurvedic rationale for its indication in liver disorders.

Preclinical and Clinical Evidence for PKK

Empirical evaluation of PKK itself is limited but encouraging. The hepatoprotective potential of Paṭolakaṭurohīnyādi Kaṣāya (PKK) has been evaluated through experimental animal studies and limited clinical investigations. In a well-documented preclinical experimental study, hepatotoxicity was induced in **Wistar albino rats** using paracetamol **at a dose of 400 mg/kg orally for seven consecutive days**. The animals were divided into normal control, disease control, preventive, curative, and test (PKK) groups, with six animals per group, as commonly adopted in experimental hepatoprotection models. **PKK was administered orally at a dose of 8.7 ml/kg/day**. In the preventive group, PKK was

given concurrently with paracetamol for seven days, whereas in the curative group, PKK was administered for seven days following paracetamol exposure, making the total study duration 14 days. Biochemical parameters including serum AST, ALT, ALP, and total bilirubin were assessed along with histopathological examination of liver tissue. The PKK-treated groups showed significant normalization of liver enzymes and bilirubin levels compared to the disease control group, along with marked improvement in hepatic architecture, indicating a protective and restorative effect against drug-induced liver injury. These findings support the hepatoprotective and antioxidant actions of PKK observed in experimental settings.[13]

Clinical evidence for PKK primarily consists of comparative trials and observational reports. An open-label randomized comparative clinical study was conducted in patients diagnosed with hepatocellular jaundice (Koṣṭhaśākhāśrita Kāmala), wherein a total of 30 patients were randomly allocated into two groups of 15 patients each. One group received Paṭolakaṭurohiṇyādi Kaṣāya, while the comparator group received Trāyaṇtyādi Kaṣāya.[14] Both formulations were administered orally in classical dosage of 15–20 ml twice daily with lukewarm water for a duration of 28 days. Clinical assessment included subjective parameters such as icterus, anorexia, fatigue, nausea, and discoloration of urine and stool, while objective evaluation was done using liver function tests including serum bilirubin, AST, ALT, and ALP before and after treatment. Both groups demonstrated statistically significant improvement in clinical features and biochemical parameters.[15] Inter-group comparison showed comparable efficacy, with PKK demonstrating pronounced Pitta śamana and Rakta prasādana effects, supporting its role in hepatocellular dysfunction.

Additionally, case-based clinical observations and small observational studies have reported the use of PKK as part of integrative Ayurvedic management in non-alcoholic fatty liver disease (NAFLD). In these reports, PKK was administered at a dose of 20 ml twice daily with lukewarm water for a duration of three months, along with other Śamana medicines and dietary and lifestyle modifications.[16] Improvements were noted in liver function parameters such as serum transaminases and bilirubin, as well as reduction in fatty infiltration on ultrasonography. Collectively, these findings pre-clinical protection in toxin-induced injury and clinical improvement in jaundice and ALD form a preliminary but tangible evidence base for PKK. However, due to methodological constraints (non-standardized formulation, small/nonsystematic trials, short follow-up, lack of control arms), they are primarily hypothesis-generating rather than confirmatory.

Modern Pharmacology of Key Constituent Herbs: Mechanistic Basis for Hepatoprotection

A major strength of the PKK formulation lies in the modern pharmacological validation of its constituent herbs. Several well-designed studies have demonstrated hepatoprotective activity, antioxidant effects, immunomodulation, and membrane stabilization mechanisms highly relevant to prevention or mitigation of hepatic injury from toxins, oxidative stress, inflammation, or metabolic overload.

Picrorhiza kurroa (Kaṭurohiṇī/Kuṭkī). Extensive modern research supports strong hepatoprotective activity of *P. kurroa*. A recent comprehensive review highlighted that picrosides I & II, kutkin, and related iridoid glycosides in *P. kurroa* act through suppression of xanthine oxidase, metal chelation, free radical scavenging, inhibition of lipid peroxidation, and modulation of inflammatory pathways. Oral administration of methanolic rhizome extracts showed protective effects in D-galactosamine/LPS-induced liver injury in mice; isolated constituents (such as picroside II, androsin, 4-hydroxy-3-methoxyacetophenone) at 50–100 mg/kg markedly reduced hepatocyte cytotoxicity, protected against TNF- α -induced toxicity, and attenuated NO production in macrophages, suggesting antioxidant, anti-inflammatory, and cytoprotective mechanisms. These data suggest a strong mechanistic basis for the hepatoprotective potential of PKK that include *P. kurroa*. [17,18]

Tinospora cordifolia (Guḍūcī). Multiple experimental studies demonstrate that extracts (aqueous, ethanolic, svarasa/hima) of *T. cordifolia* significantly reduce elevations of liver enzymes (AST, ALT, ALP), restore normal histology, and increase antioxidant enzyme activity (e.g., superoxide dismutase, catalase), while decreasing lipid peroxidation in carbon tetrachloride (CCl₄)- or paracetamol-induced liver injury models. [19] One study reported that ethanolic extracts were most effective, though even aqueous preparations showed significant benefit. Histopathological analysis confirmed reduction of necrosis and inflammatory infiltration. These findings support Guḍūcī's classical classification as Rasāyana and Yakṛt-supporting herb, and validate its inclusion in PKK as a hepatoprotective and detoxifying agent. [20]

Supporting Evidence for Polyherbal Formulation

Systematic reviews of medicinal plants with hepatoprotective activity often list *P. kurroa*, *T. cordifolia*, and other taxa present in PKK among promising candidates, underscoring that herbal combinations may yield additive or synergistic effects, especially in complex, multifactorial liver diseases. [21] This supports the classical polyherbal

rationale where multiple herbs in a decoction address various pathological aspects (oxidative stress, inflammation, bile flow, metabolic disturbance).

Thus, the modern pharmacological profile of PKK's ingredients aligns strongly with the observed preclinical and clinical hepatoprotective effects, offering a scientifically plausible mechanistic framework bridging traditional Ayurvedic knowledge and contemporary hepatology.

Safety, Standardization, and Regulatory Considerations

While constituent herbs such as *T. cordifolia* and *P. kurroa* have shown good safety profiles in experimental studies, widespread clinical use of PKK requires rigorous evaluation of long-term safety, herb–drug interactions (especially in patients on allopathic medications), dose standardization, microbial safety of decoctions, and batch-to-batch consistency. The lack of clinical reports describing serious adverse effects is encouraging but not sufficient; most trials are short-term (weeks), involve small numbers, and lack systematic monitoring. Additionally, standardization of the decoction (herb authentication, part used, ratio, extraction volume, concentration, storage conditions) is rarely described in published clinical reports, undermining reproducibility and generalizability.[22] For PKK to be accepted in integrative hepatology, efforts must be made to develop pharmacopeial standards for preparation, to document active marker compounds (e.g., picrosides, alkaloids, flavonoids), and to conduct controlled toxicity and herb–drug interaction studies.[23]

Limitations of Current Evidence

Despite encouraging signals, several critical limitations constrain any strong recommendation for PKK's routine clinical use. First, the preclinical evidence remains limited to a few studies (e.g., paracetamol-induced hepatotoxicity in rats), and lacks exploration in chronic models (e.g., repeated toxin exposure, alcohol, fatty liver, cholestasis, fibrosis). Second, clinical trials are small ($n \approx 20\text{--}30$), non-blinded or uncontrolled, of short duration (4–8 weeks), and often combined with lifestyle changes; hence placebo effect, spontaneous recovery, and regression to the mean cannot be excluded. Third, formulation heterogeneity and lack of phytochemical standardization make cross-study comparisons difficult and prevent replication. Fourth, long-term outcomes—such as fibrosis regression, cirrhosis stabilization, liver-related morbidity or mortality—have not been studied. Finally, absence of pharmacokinetic data, poor reporting of safety/adverse events, and lack of herb–drug interaction data raise concerns for large-scale or long-term application.[15]

Future Directions and Research Recommendations

To establish PKK from a traditionally used decoction towards an evidence-based hepatoprotective medicine, a coordinated research agenda is required.

1. Rigorous phytochemical standardization should be conducted: identify, quantify, and validate marker compounds (e.g., picrosides, glycosides, alkaloids, flavonoids) via techniques such as HPLC, LC-MS, or NMR; ensure batch-to-batch consistency.
2. Preclinical studies in chronic/clinically relevant models (e.g., alcohol-induced liver injury, NAFLD, cholestasis, fibrosis, repeated toxin exposure) should be prioritized; study endpoints should include oxidative stress markers, inflammatory cytokines, bile flow, histopathology, fibrosis markers, and regeneration indices.
3. Toxicology and herb–drug interaction studies should be systematically carried out, especially since liver disease patients often take multiple medications.
4. **Randomized, double-blind, placebo-controlled clinical trials with adequate sample size and longer follow-up (6–12 months), using standardized PKK preparation and objective endpoints (LFTs, imaging/fibrosis markers, quality-of-life) are essential.**
5. Pharmacokinetic (PK)/pharmacodynamic (PD) studies to understand absorption, bioavailability, metabolism, excretion, and active dose–response relationships would facilitate dosing optimization.
6. Lastly, regulatory and quality frameworks should be developed (pharmacopeial monographs, decoction preparation guidelines, microbial safety, storage/stability).

Conclusion

Paṭlakāṭurohiṇyādi Kaṣāya demonstrates significant potential as a hepatoprotective Ayurvedic formulation, supported by its classical Rasapañcaka-based rationale and emerging preclinical and clinical evidence. Experimental studies indicate biochemical and histological protection against hepatotoxic injury, while limited clinical studies suggest improvement in liver function and symptomatic relief in Kāmala and fatty liver disorders. However, the current evidence remains preliminary due to small sample sizes, short study durations, non-blinded designs, and lack of formulation standardization. Future research should focus on rigorous phytochemical standardization, long-term safety assessment, pharmacokinetic evaluation, and well-designed randomized controlled clinical trials to establish PKK as an evidence-based hepatoprotective agent.

Declarations

Conflict of Interest: The author declares that they have no conflicts of interest related to this work.

Funding / Financial Support: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

8

Author Contributions: The author has contributed to the conception, design, data collection, analysis, drafting, and approval of the final manuscript.

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Ethical Approval: Not Applicable

Data Availability Statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Acknowledgements: The authors would like to acknowledge the support of their institution, colleagues, and technical staff who contributed to this work.

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