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中医药防治高尿酸血症伴肾功能不全的研究进展：机制、疗效与临床评价

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摘　要

高尿酸血症(hyperuricemia, HUA)不仅是痛风的重要致病因素，亦是慢性肾脏病(chronic kidney disease, CKD)进展的独立危险因素。部分患者进一步发展为高尿酸血症伴肾功能不全(hyperuricemia with renal insufficiency, HURI)及尿酸性肾病(uric acid nephropathy, UAN)。目前西医治疗主要依赖黄嘌呤氧化酶抑制剂和尿酸排泄药物，但长期应用易出现不良反应、疗效波动及高复发率等问题，亟需探索多靶点干预的替代治疗方案。近年来，基于中医药“多成分、多靶点”协同作用的特点，围绕“降尿酸–抗炎–肾保护”全链路干预的研究逐渐成为热点。基础研究表明，中药可通过调控尿酸代谢(如抑制黄嘌呤氧化酶、调节URAT1、GLUT9等转运体)、抑制炎症反应(如干预NLRP3/NF-κB信号通路)、延缓肾脏纤维化(如阻断TGF-β/Smad3信号通路)等多重机制发挥综合防治作用。临床研究亦证实，辨证施治的中药方剂如健脾渗湿解毒汤、健脾益肾祛瘀汤联合西药治疗，可有效降低血尿酸水平，改善肾功能(eGFR、Scr)及炎症指标，且具有良好的安全性。然而，现有研究普遍存在样本量小、缺乏严谨对照、结局指标单一等问题。未来应遵循PICOS原则，设计高质量、多中心、随机对照临床试验，以进一步阐明中医药在高尿酸血症相关肾损伤防治中的作用机制及临床价值。

关键词

中医药，高尿酸血症，肾功能不全，尿酸性肾病，尿酸代谢，炎症，肾脏保护，临床研究

Research Progress on Traditional Chinese Medicine in the Prevention and Treatment of Hyperuricemia with Renal Insufficiency: Mechanisms, Efficacy, and Clinical Evaluation

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Abstract

Hyperuricemia (HUA) is not only an important pathogenic factor of gout, but is also an independent risk factor for the progression of chronic kidney disease (CKD). Some patients may further develop hyperuricemia with renal insufficiency (HURI) and uric acid nephropathy (UAN). At present, conventional Western medical treatment mainly relies on xanthine oxidase inhibitors and uricosuric agents. However, long-term use may be associated with adverse reactions, variable efficacy, and a high recurrence rate. Therefore, alternative multi-target therapeutic strategies need to be further explored. In recent years, Traditional Chinese Medicine (TCM), characterized by multi-component and multi-target synergistic effects, has attracted increasing attention for its comprehensive intervention in uric acid reduction, anti-inflammation, and renal protection. Basic research has shown that Chinese herbal medicine may exert comprehensive preventive and therapeutic effects through multiple mechanisms, including regulation of uric acid metabolism, such as inhibition of xanthine oxidase and modulation of urate transporters including URAT1 and GLUT9; suppression of inflammatory responses, such as regulation of the NLRP3/NF-κB signaling pathway; and delay of renal fibrosis, such as inhibition of the TGF-β/Smad3 signaling pathway. Clinical studies have suggested that syndrome differentiation-based Chinese herbal prescriptions, such as Jianpi Shenshi Jiedu Decoction, Jianpi Yishen Quyu Decoction, combined with Western medicine, may reduce serum uric acid levels, improve renal function indicators including eGFR and Scr, and regulate inflammatory markers, with favorable short-term safety. However, current studies are generally limited by small sample sizes, lack of rigorous controls, and relatively narrow outcome indicators. Future studies should follow the PICOS principle and conduct high-quality, multicenter randomized controlled trials to further clarify the mechanisms and clinical value of TCM in the prevention and treatment of hyperuricemia-related kidney injury.

Keywords

Traditional Chinese Medicine, Hyperuricemia, Renal Insufficiency, Uric Acid Nephropathy, Uric Acid Metabolism, Inflammation, Renal Protection, Clinical Research

1. 引言

高尿酸血症伴肾功能不全(hyperuricemia with renal insufficiency, HURI)系指高尿酸血症患者合并肾小球滤过率下降或血清肌酐升高等肾功能减退表现的临床状态，其发病机制涉及尿酸盐晶体沉积、肾脏血流动力学改变、氧化应激及炎症损伤等多个环节[1]-[3]。尿酸性肾病(uric acid nephropathy, UAN)则为病理学诊断，特指尿酸盐于肾组织沉积所致的结构性损害，是 HURI 的重要病理类型之一，但并不能涵盖所有高尿酸血症合并肾功能减退的临床情形[4] [5]。两者在临床实践中高度重叠；就中医病机而言，均以脾肾亏虚为本、湿浊瘀毒蕴结为标，辨治原则具有较高的一致性。鉴于现有临床研究多以尿酸

性肾病为纳入诊断，本文将两者纳入统一框架加以综述，以期较为完整地梳理中医药在该领域的研究现状与进展。

2. 高尿酸血症伴肾功能不全的西医治疗现状

尿酸是嘌呤代谢的最终产物，肾脏在调节循环尿酸水平中发挥关键作用：约 90%的滤过尿酸被重吸收，且肾脏负责机体 60%~70%的尿酸排泄功能。异常的肾脏尿酸处理被认为是高尿酸血症及痛风的重要病理生理基础[6]。近几十年来，全球高尿酸血症患病率显著上升，其与高血压、代谢综合征及慢性肾脏病密切相关，对公共卫生构成严重负担。然而，痛风或高尿酸血症患者中肾功能受损并不少见，部分患者可进一步进展为终末期肾病[2]。血清尿酸升高通常预示肾功能进行性损伤与障碍[7]。这可能源于尿酸钠晶体沉积诱导的氧化应激、内皮功能障碍、炎症反应及肾素–血管紧张素系统激活等机制[8]-[10]。同时，在慢性肾脏病患者中，痛风及高尿酸血症的发生率分别高达 25%和 60% [11]。目前关于高尿酸血症在慢性肾脏病进展或恶化中的因果关系尚无定论，但降低血清尿酸水平可能有助于延缓肾脏疾病进展[12] [13]。高尿酸相关肾损伤可表现为肾功能减退、尿酸结石、蛋白尿等肾脏损害，而痛风性关节炎是关节表现，这提示高尿酸血症、晶体沉积与慢性肾脏损伤之间存在相互交织的疾病谱特征[4]。目前，对高尿酸血症伴肾功能损害的西医治疗主要集中于降低血清尿酸，其作用机制可分为三类：(1) 黄嘌呤氧化酶抑制剂，通过抑制黄嘌呤氧化酶活性以减少尿酸生成[14]；(2) 促进尿酸外排药物，通过增加肾小管尿酸盐分泌或抑制重吸收以提升尿酸排泄；(3) 重组尿酸酶，利用外源性酶将尿酸转化为更易排出的尿囊素。美国、欧洲及英国风湿病学会指南一致推荐别嘌呤醇作为一线降尿酸药物，适用于包括肾功能不全患者在内的各类人群，因其成本低、给药便捷而被广泛采用[15]-[17]。临床研究表明，别嘌呤醇可显著降低轻至中度慢性肾病患者的血清尿酸水平，并延缓肾功能恶化[18] [19]，但极少数病例报告其可引发严重的超敏反应，包括皮疹伴嗜酸性粒细胞增多、白细胞计数升高、发热、肝炎及进展性肾衰竭，尽管发病率极低，却可能致死，增加了用药风险[20]。非布司他作为首个非嘌呤类黄嘌呤氧化酶抑制剂，自 2009 年获批以来，其降尿酸疗效与别嘌呤醇相当且耐受性良好[21]。尽管早期对其心血管安全性存在担忧，但柳叶刀发表的长期随访研究显示，非布司他使用并不增加死亡率或严重不良事件风险[22]，然而，近期关于其急性肝损伤风险的报道提醒临床应用需更加谨慎[23]。综上，基于现有药物的安全性与耐受性局限性，开发新型、长期可用且安全性更佳的降尿酸药物仍然刻不容缓。与此同时，传统医药在改善高尿酸血症合并肾功能不全及尿酸性肾病方面已有较多研究积累，其丰富的活性成分和多靶点作用模式，为未来补充或替代疗法的研发提供了良好前景。

3. 中医药防治高尿酸血症伴肾功能不全的理论基础

传统中医并无“尿酸”这一概念，然而，依据其关节肿痛、水肿、泡沫尿等症状表现，此类病症可归类于“痛风”“痹证”“水肿”“淋证”等中医范畴。关于本病的病名及病因病机，其最早阐述可见于《黄帝内经》。其中《素问·痹论》明确指出：“风寒湿，三气杂至合而为痹也。”对于本病的临床表现，《金匮要略·中风历节病脉证并治》有相关描述：“诸肢节疼痛，身体魁羸，脚肿如脱。”这指出了其主要表现为肢体关节疼痛、身形消瘦且关节肿大。针对无关节疼痛症状的痹症成因，《素问·痹论》也有阐述“得邪则气缓，虽痹而不痛。”这主要是由于风寒湿邪侵袭筋骨、皮肤、血脉、肌肉，阻碍了气机的运行，导致气机迟缓，从而形成痹症，但并不伴有明显疼痛。同时，《素问·痹论》还提及痹症可通过传变累及脏腑，并对其临床表现加以阐述，这为现代运用中医学治疗慢性高尿酸血症伴肾功能不全提供了理论依据。如篇中所述“其不通不仁者，病久入深，荣卫之行涩，经络时踈，故不通”“五藏皆有

合，病久不去者，内舍于其合也”“凡痹之客五藏也者，肾痹者，善胀，尻以代踵，脊以代头”“淫气遗溺，痹聚在肾”。这些内容指出，痹症日久会侵袭人体脏腑，若累及肾脏，可出现腹部胀满、肢节变形、小便排泄失常(如尿多或尿少)等表现。在治疗方面，多部古籍中的方剂至今仍被沿用，也是临床治疗本病的常用方剂，例如《金匮要略》中的桂枝芍药知母汤、白虎加桂汤，《备急千金要方》中的独活寄生汤，以及《成方便读》中的四妙丸等。

多位医家对尿酸性肾病的病因病机及治疗见解各异。周珂教授[24]认为，该病的水湿、痰浊、瘀毒由“血浊”进展而来，因脾肾亏虚致浊邪内生、气机血行不畅，实邪伤正、肾络不通，他以“血浊”为纲分期论治，潜伏期脾肾气虚、血浊内蕴，治以补脾益肾、清利血浊；加重进展期湿热瘀阻，治以清利湿热、行血泄浊；张佩青教授[25]指出湿浊伤肾，瘀阻三焦是尿酸性肾病经久不愈、病情缠绵之根本，属标实本虚之候，在使用分消走泄法治疗时应辨明病位，并据病程选方用药；国医大师皮持衡教授认为[26]尿酸性肾病伏邪的来源主要分为先天和后天，且二者相互作用，搏结难解，致后期积重难返；高彦彬教授认为慢性尿酸性肾病是由痛风日久，久痛入络，久病入络，久病及肾而形成的肾脏并发症，本病病位在肾络，属于中医“络病”范畴[27]。虽各医家对尿酸性肾病的认识有所侧重，但均强调本病属本虚标实、虚实夹杂的病理特点。治疗上多遵循祛邪与扶正并重的原则，为中西医结合提供了多元的理论依据与实践指导。

4. 中医药防治高尿酸血症伴肾功能不全的基础研究

4.1. 影响尿酸代谢

中药在调控尿酸代谢方面的作用主要体现在促进尿酸排泄和抑制尿酸生成两个方面。中药降尿酸作用主要通过两个靶点实现：一是抑制肝脏黄嘌呤氧化酶活性，二是调节肾脏尿酸转运蛋白的表达[28]。其中抑制尿酸的合成主要包括通过影响尿酸合成过程中的关键酶，如黄嘌呤氧化酶(XO)、次黄嘌呤－鸟嘌呤磷酸核糖基转移酶(HGPRT)等来降低尿酸水平[29]-[31]。通过调节尿酸转运蛋白，如尿酸转运蛋白 1 (URAT1)、葡萄糖转运蛋白 9 (GLUT9)、有机阴离子转运蛋白(OAT1/3)、以及 ATP 结合盒 G 亚家族成员 2 (ABCG2)等，是促进尿酸排泄的重要机制[32]-[35]。

4.2. 改善肾功能

在肾功能保护方面，中药通过多途径、多靶点的综合作用展现出显著的优势。中药可以通过改善肾小球滤过功能、增强肾血流量，修复肾脏组织损伤、改善肾脏功能。其机制之一是通过抗氧化作用，减少氧化应激对肾小管的损伤，促进肾组织的再生和修复[36] [37]，此外，中药复方还可以通过调节 TGF-β1/SMAD3 信号通路，改善高尿酸血症相关的肾功能不全，并有效减缓肾脏纤维化的进程[38]。

4.3. 调节炎症反应

越来越多的研究关注使用草药治疗炎症性疾病，尤其是高尿酸血症，因为这些草药通过抑制氧化应激反应，减少活性氧(ROS)的产生，进而发挥抗炎作用[39]。肾气汤和加味四妙汤等方剂可通过多种途径改善高尿酸血症相关炎症损伤：一方面抑制 TNF-α、IL-1β 等炎症因子的释放，另一方面增强超氧化物歧化酶(SOD)等抗氧化酶的活性，从而减轻炎症反应和氧化应激[40] [41]。进一步研究表明，部分草药可通过抑制 NLRP3 炎性小体的激活，减轻肾脏炎症，并降低血尿酸水平(如促进排泄或减少生成)，从而有效缓解高尿酸血症[42] [43]。

通过对现有文献的梳理发现，中药在尿酸性肾病的治疗中呈现多成分、多靶点、多途径的作用特点。基础研究聚焦于中药的药理活性及分子机制，其中四妙散/加味、痛风相关胶囊等高频出现，聚焦抗炎、降尿酸及肾脏保护机制。

总之，高尿酸血症可通过尿酸负荷增加、尿酸盐结晶沉积、氧化应激、内皮功能障碍、炎症反应、NLRP3 炎性小体激活、RAAS 激活及 TGF-β/Smad 介导的纤维化通路，导致肾小球/肾小管损伤、肾纤维化及肾功能不全；中医药可通过调控嘌呤代谢、抑制 ROS/NF-κB/NLRP3 炎症氧化应激反应、调节尿酸转运蛋白、减轻纤维化通路激活及保护肾小球/肾小管等多靶点、多通路干预疾病进程(如图 1 所示)。

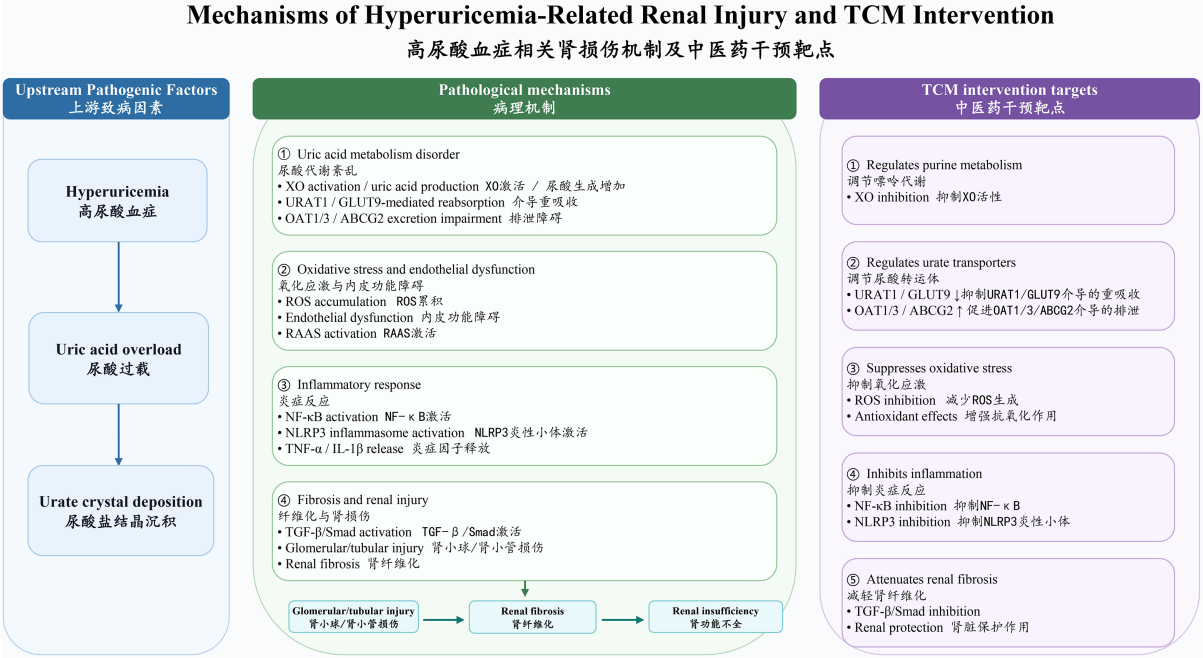

Figure 1. Pathological mechanisms of hyperuricemia-related renal injury and potential intervention targets of traditional Chinese medicine
图 1. 高尿酸血症相关肾损伤的病理机制及中医药干预靶点

5. 中医药防治高尿酸血症伴肾功能不全的临床研究

多项临床研究证实不同中药方剂对尿酸性肾病各证型的疗效。符芸瑜等人[44]将 168 例尿酸性肾病湿热蕴结证患者分为两组，对照组行西医常规治疗，观察组加用健脾渗湿解毒汤，均治疗 28 天，结果显示观察组相关指标改善更明显，总有效率更高，研究表明该汤可通过多途径改善肾功能、提升疗效。针对临床常见的脾虚湿热证，戚晨云等人[45]自拟化痹健脾康肾方，发现其改善患者肾功能疗效优于单纯西药。张琦等人[46]研究显示，健脾益肾祛瘀汤与非布司他联合治疗，在保护肾功能、降血尿酸、减尿蛋白方面效果更优。对于脾肾亏虚证患者，黄雪红等人[47]发现痛风合剂 3 号方治疗能提升疗效、缓解症状，尤其在改善肾功能和减轻炎症反应方面效果显著，且安全性高。程氏萆薢分清饮有清热利湿等功效，配伍相关药材可增强清利湿热之效，李晓倩等人[48]研究表明其联合非布司他治疗湿浊瘀阻型患者，改善肾功能等指标效果更优，不良反应少且安全可靠。综上，现有小样本研究提示，不同中药方剂在尿酸性肾病不同证型中可能具有一定疗效，且与西药联合应用时在部分结局上显示出潜在优势。未来需深入解析方剂作用机制，并通过大样本多中心临床研究进一步验证其普适性，为中医药防治本病提供更坚实的循证依据。

然而现有研究虽多为临床方向，包括随机对照、病例观察、个案报道等，方剂以补肾、利湿、化浊为主，均示疗效，但存在诸多问题：多数研究以西医治疗为对照，且多为单一西医治疗，未采用西医联合中医安慰剂对照，而安慰剂效应涉及经典条件反射、期望等多因素，空白治疗不等于安慰治疗，开放标签空白治疗或影响患者期望[49] [50]，建议后续研究设模拟中药安慰组，以减少非特异性作用对结局的干

扰；现有研究多报告血清肌酐、血尿酸、肾小球滤过率等肾脏相关结局的治疗前后比较，但临床研究有效性评估需结合临床意义，组间差值报告必不可少，其可减少基线不一致问题，清晰反映改善程度，利于评估干预有效性[51]，故建议增加组间治疗前后差异报告；现有研究多为小样本，虽提及随机方法，但随机流程、统计方法简单，缺乏分配隐藏及盲法描述，可能引发实施偏倚、测量偏倚，导致低质量研究增多[52]；关于中西医联合比较，析因设计更适用于补充替代医学干预，可反映主效应、交互效应及总效应，但需更复杂设计及更大样本量[53]。

6. 小结

综上所述，通过对高尿酸血症伴肾功能不全的系统梳理可发现，现有基础研究与临床研究提示，中药在降低血尿酸水平、改善肾功能及减轻炎症反应等方面具有潜在获益，其作用机制主要通过多种活性成分共同作用于抑制尿酸生成、促进尿酸排泄及肾脏保护等多个环节。然而，中医药在该领域的推广应用仍面临诸多挑战。目前临床研究普遍存在质量不高、研究设计不规范(如分组方式、样本量估算、结局指标选择欠合理)及缺乏研究注册等问题，影响了现有证据的科学性与可靠性。同时我们也注意到，中医药在该领域的临床转化仍受制于若干现实问题，如中药材批间质量差异对研究可重复性的影响、辨证论治的个体化特点与临床试验标准化等问题。未来可在方剂多靶点协同的量效关系、证型与疗效应答的生物学基础、中西药联合用药的安全性等方面开展更深入的研究。

因此，建议未来开展高质量、多中心的随机对照试验，规范研究流程与方法学，以更充分地发挥中医药治疗优势，并为高尿酸血症伴肾功能不全的中医药防治提供更高等级的循证医学证据支撑。

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