

Integrative Use of Belimumab and Individualized Traditional Chinese Medicine in Refractory Pediatric Lupus Nephritis: A Case Report

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Background: Pediatric lupus nephritis (LN) is characterized by rapid progression and presents considerable therapeutic challenges. Standard immunosuppressive regimens may be insufficient in refractory cases, which are often marked by frequent relapses and poor long-term outcomes. Belimumab, a monoclonal antibody targeting B lymphocyte stimulator (BLyS), and individualized traditional Chinese medicine (TCM) interventions have demonstrated respective benefits in LN management. This case report describes the clinical course of a child with refractory LN that was managed using an integrative approach combining belimumab with individualized TCM therapy.

Case Presentation: A pediatric patient with LN presented with persistent gross hematuria, conventional glucocorticoids immunosuppressants and hydroxychloroquine treatment failed to achieve adequate disease control. Subsequent administration of belimumab in combination with an individualized TCM formulation led to notable clinical improvement, including significant reductions in proteinuria and hematuria, along with a marked decline in systemic lupus erythematosus disease activity. Background medications were gradually tapered during the treatment course. No serious adverse effects were observed, and clinical remission was sustained throughout the follow-up period.

Conclusion: The combination of belimumab and individualized TCM may safely and effectively control refractory childhood LN, reduce corticosteroid dosage, and sustain remission; however, validation through studies with larger sample sizes is required.

Keywords: biologic agents, glucocorticoids, gross hematuria, immunosuppressants, integrative medicine, lupus nephritis

Introduction

Lupus nephritis (LN), a renal manifestation of systemic lupus erythematosus (SLE), represents the most common and clinically significant renal complication associated with this autoimmune disease. Clinical manifestations vary from asymptomatic hematuria and/or proteinuria to nephrotic syndrome, and in more severe cases, rapidly progressive glomerulonephritis accompanied by renal dysfunction.¹ The primary therapeutic objectives include the long-term preservation of renal function, prevention of disease recurrence, and improvement in both quality of life (QoL) and overall survival.

Standard therapeutic regimens typically consist of glucocorticoids, immunosuppressants, and hydroxychloroquine. According to the 2020 Chinese Guidelines for the Diagnosis and Treatment of SLE, the use of biologic agents is recommended for patients with SLE who demonstrate insufficient response.² Despite these measures, a subset of pediatric patients with LN demonstrate resistance to conventional therapy, characterized by frequent disease flares and

compromised QoL. Recent comprehensive reviews emphasise that cLN is not merely “adult LN in smaller bodies”: children exhibit more vigorous autoimmunity, higher relapse rates and distinct pharmacokinetics that mandate dedicated treatment algorithms.³ This report describes the clinical course of a pediatric patient with refractory LN, whose disease activity remained inadequately controlled under standard therapy. The introduction of belimumab, in combination with an individualized traditional Chinese medicine (TCM) regimen, was followed by significant clinical improvement.

Case Presentation

Present Illness and Physical Examination

An 8-year and 5-month-old girl was admitted to the department in December 2021 due to abnormal urinalysis findings persisting for more than three months. Her medical history was notable for allergic rhinitis and recurrent respiratory tract infections. In late August 2021, she experienced a sudden onset of gross hematuria without associated fever, rash, dysuria, urinary urgency, or peripheral edema. A history of recurrent oral ulceration was also reported. Initial evaluation at a local hospital revealed 4137 red blood cells/ μ L in urinary sediment and 3+ proteinuria on urinalysis. A urinary tract infection was diagnosed, and a one-week course of empirical antibiotic therapy was prescribed. Despite treatment, gross hematuria persisted, prompting referral for further evaluation. At the time of admission, the patient exhibited low-grade fever and oral mucosal ulceration. There were no complaints of cough, nasal congestion, malar rash, arthralgia, photosensitivity, or neuropsychiatric manifestations. Reported symptoms included abdominal distension and pain, occasional nausea, dry mouth, and halitosis. Appetite and sleep patterns were stable. Bowel movements were loose, occurring twice daily. Gross hematuria was not observed at the time of presentation, and there were no symptoms of urinary frequency, urgency, or dysuria.

Physical examination findings included a body weight of 21 kg and a height of 120 cm, both below the 3rd percentile for age. Blood pressure was measured at 79/44 mmHg. The patient was alert and cooperative, and appeared pale, with noted short stature. No malar rash was present. Examination of the oral cavity revealed dry, desquamated lips and oral mucosa, with a solitary ulcer on the right buccal mucosa and one dental caries. The tongue appeared red with a thick yellow coating at the root, and the pulse was thin and rapid. No obvious abnormalities were observed during the physical examination of other systems.

Auxiliary Examinations and Diagnosis

Complete blood count results indicated normal hemoglobin concentration and platelet count. Complement analysis revealed a markedly reduced C3 level (0.09g/L), while C4 (0.17g/L), immunoglobulin A (IgA 1.09 g/L), immunoglobulin M (IgM 0.19g/L), and immunoglobulin G (IgG 6.93g/L), levels were also significantly decreased. The antinuclear antibody (ANA) titer was 1:320. Serologic testing for anti-double-stranded (ds) DNA antibody, anti-Smith (Sm) antibody, anti-SSA antibody, anti-SSB antibody, anticardiolipin antibody, anti-neutrophil cytoplasmic antibody, anti-myeloperoxidase antibody, and anti-proteinase 3 antibody yielded negative results. The 24-hour urine protein quantification was 330.6 mg/24h at baseline. Genetic testing for monogenic lupus and underlying immunodeficiencies was not performed.

Renal biopsy findings demonstrated immune complex deposition, with immunofluorescence staining showing IgM++, C3c+++, C4c+++, IgG+++, and complement C1q+++ in a granular pattern along glomerular capillary walls and within mesangial regions. The pathological classification criteria are established according to the 2003 version issued by the International Society of Nephrology/Renal Pathology Society (ISN/RPS).⁴

Pathological diagnosis: Lupus nephritis (Class III).

- Final diagnoses:
 - a. Western medicine diagnosis: Lupus nephritis (Class III).
 - b. TCM diagnosis: Yin-Yang toxin pattern, characterized by spleen and kidney deficiency with internal retention of damp-heat.

Treatment Course

Phase I

Initial treatment included intravenous administration of methylprednisolone sodium succinate at a dose of 32 mg/day (2mg/kg/day) for four days, followed by oral prednisone acetate tablets at 40 mg/day (2mg/kg/day). Additional oral medications included hydroxychloroquine (50 mg twice daily [5mg/kg/day]), mycophenolate mofetil (0.25 g twice daily [25mg/kg/day]), and fosinopril sodium (10 mg/day [0.5mg/kg/day]). Within approximately 10 days of initiating therapy, gross hematuria resolved, and proteinuria became undetectable. The patient was discharged in stable condition and remained clinically stable for approximately one month. Prednisone acetate tablets were tapered at a rate of 5 mg per week. Upon reaching a dose of 25 mg/day, disease recurrence occurred, characterized by 2+ proteinuria, 978.80 red blood cells/ μ L, and 1+ white blood cells in urine sediment. Methylprednisolone sodium succinate pulse therapy (420 mg/day) was administered for three days. The dosage of mycophenolate mofetil was adjusted to 0.75 g in the morning and 0.5 g in the evening. Despite these adjustments, proteinuria persisted, serum complement C3 remained low, and fever developed.

Phase II

At the onset of fever, high-sensitivity C-reactive protein was elevated to 31.12 mg/L, consistent with acute infection. Supportive management included anti-infective therapy, urine alkalinization, and hydration over a five-day period, resulting in fever resolution and a marked decrease in urinary red blood cells. The patient's condition stabilized, and the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI)⁵ score decreased from 13 to 6, indicating mild disease activity.

Following a comprehensive clinical evaluation and parental consent, belimumab treatment was initiated at a dosage of 10 mg/kg per infusion. The first three infusions were administered biweekly, followed by monthly maintenance infusions, with a planned treatment duration of 52 weeks. Concurrently, an individualized TCM formulation was administered orally. During the recurrence stage, the modified prescription combining Ganlu Disinfection Pill and Fengsu Pill consists of ingredients such as talc, *Scutellaria baicalensis*, *Artemisia capillaris*, *Acorus tatarinowii*, *Fritillaria thunbergii*, *Agastache rugosa*, *Forsythia suspensa*, *Dryopteris vulgaris*, and *Phellodendron amurense*. The drugs used in this stage are predominantly of bitter and cold nature, and long-term administration may easily impede the transportation and transformation functions of the spleen and stomach. In the later stage of the disease, a modified version of Liuwei Dihuang Pills was prescribed. The ingredients comprise *Rehmannia glutinosa*, *Dioscorea opposita*, *Cornus officinalis*, *Poria cocos*, *Alisma orientale*, *Paeonia suffruticosa*, *Cuscuta chinensis*, *Cyperus rhizoma*, and Red Peony Root. This prescription has a mild property and can moderately tonify the three jiao. No adverse reactions have been observed.

By January 2023, the patient had completed 15 belimumab infusions over the 52-week period. The disease remained stable without evidence of recurrence or involvement of additional organ systems. Tapering of prednisone acetate was continued. Compared to the pre-treatment phase, marked clinical improvement was observed, including resolution of oral ulcers, hematuria, and proteinuria. Growth parameters improved, with an annual height gain of 4 cm and a weight increase of 3 kg. At the most recent assessment, the SLEDAI score was 2, consistent with SLE activity, and the overall condition continued to improve.

Efficacy Evaluation

Following the initiation of belimumab in combination with an individualized TCM regimen, sustained clinical improvement was observed in the patient. Urinary red and white blood cell counts demonstrated a progressive decline, reaching normal levels by week 40 (Figure 1). Both 24-hour urinary protein and microalbumin levels continuously decreased and returned to within normal limits by week 8 (Figure 2). Serum complement levels exhibited only minimal improvement throughout the treatment period (Figure 3).

The SLEDAI score decreased following initiation of therapy, with two transient elevations attributed to respiratory infections. From week 32 onward, a steady decline in the SLEDAI score was observed, indicating maintenance of mild disease activity (Figure 4). No recurrence of mucosal ulceration, malar rash, gross hematuria, or neuropsychiatric manifestations was reported during the observation period. Gastrointestinal symptoms, including abdominal distension, nausea, dry mouth, and halitosis, showed substantial improvement. The 24-hour urine protein quantification was 27.5 mg/24h after 52 weeks.

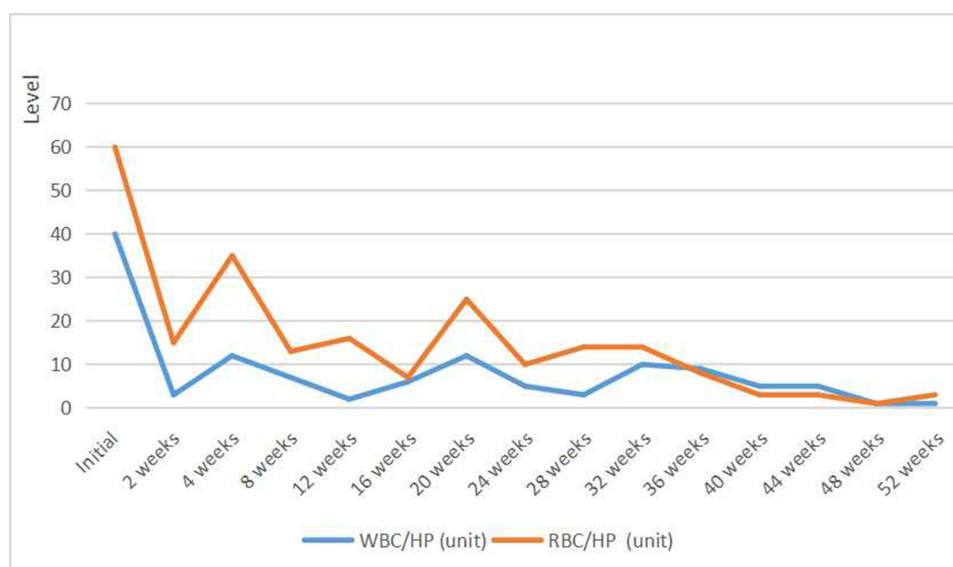


Figure 1 Changes in urinary red blood cells and white blood cells before and after initiation of combined belimumab and syndrome-differentiated traditional Chinese medicine (TCM) treatment.

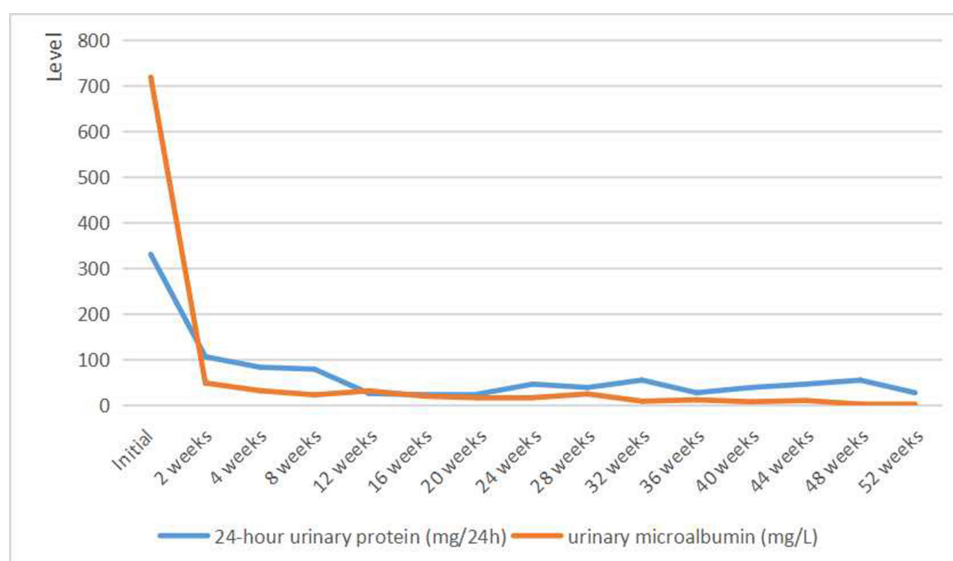


Figure 2 Reduction in 24-hour urinary protein and microalbumin levels before and after treatment.

Glucocorticoid therapy was successfully tapered to a low-dose maintenance regimen without disease flare. Comprehensive clinical data are presented in [Table 1](#).

Discussion

This case involves a patient with LN. Initial management followed the 2016 Evidence-Based Guidelines for the Diagnosis and Treatment of Lupus Nephritis, involving high-dose pulse therapy with intravenous methylprednisolone sodium succinate. Despite adherence to guideline-recommended therapy, the clinical response remained inadequate.

Subsequent reassessment of disease activity prompted consideration of alternative therapeutic strategies. According to the 2020 Chinese Guidelines for the Diagnosis and Treatment of SLE, the use of biologic agents is recommended for patients with SLE who demonstrate insufficient response, intolerance, or frequent relapse during treatment with glucocorticoids and/or conventional immunosuppressive agents.^{2,6}

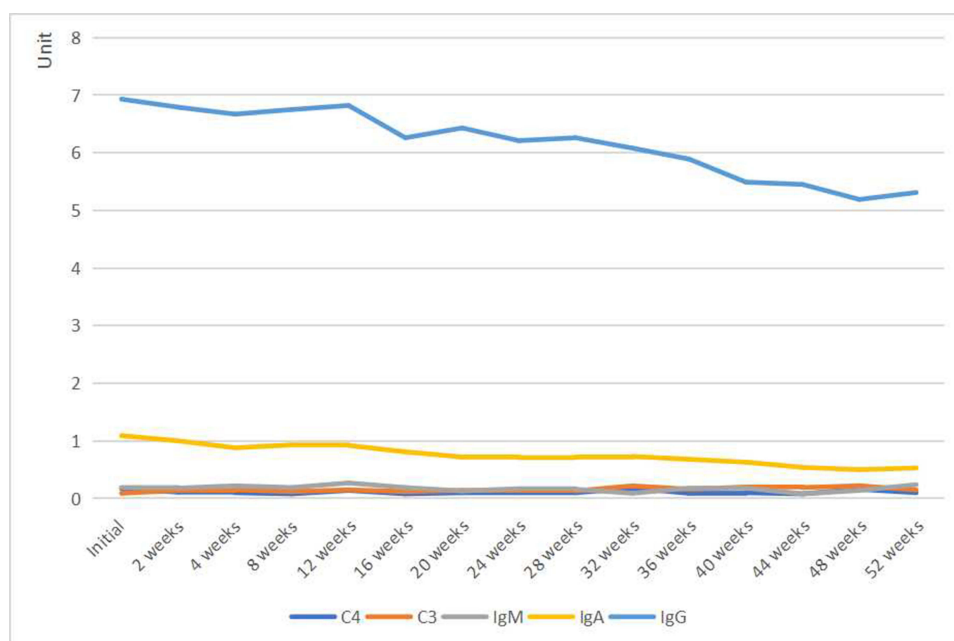


Figure 3 Serum complement C3 and C4 levels over the treatment course with belimumab and syndrome-differentiated TCM.

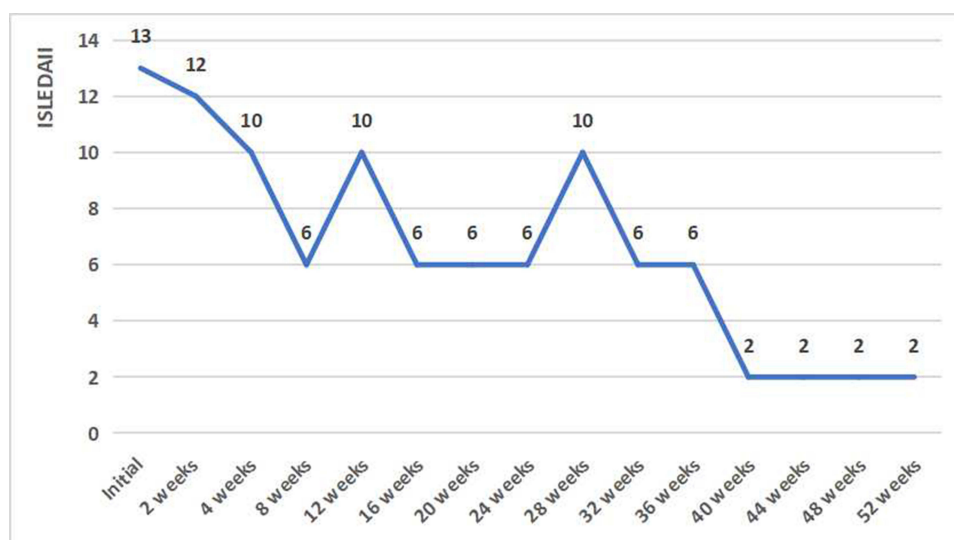


Figure 4 Changes in SLEDAI scores before and after treatment.

The 2024 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Management of Lupus Nephritis supports this approach, citing post hoc analyses that indicate the addition of belimumab to standard therapy in patients with active LN is associated with reduced relapse rates and slower deterioration in renal function compared with standard immunosuppressive therapy alone.⁷

To achieve disease control, prevent recurrence, and enhance QoL, belimumab was incorporated into the standard treatment regimen in combination with a syndrome-differentiated TCM formula. Following 52 weeks of combined therapy, the SLEDAI score decreased from 13 to 2, indicating a transition from moderate to sustained mild disease activity. Both hematuria and proteinuria resolved and remained within normal limits, without recurrence of mucosal ulceration or involvement of additional organ systems. Glucocorticoids were successfully tapered to a low-dose maintenance regimen.

Table 1 Improvement of Main Clinical Manifestations and Medication Adjustments Before and After Treatment

Treatment Time	Clinical manifestations			Treatment	
	Fever	Ulcers	Rash	Glucocorticoids	Concomitant Medications
Initial	Present	Present	Absent	25mg/qd	TCM; mycophenolate mofetil 0.75 g morning, 0.5 g evening; hydroxychloroquine 50 mg twice daily; fosinopril 10 mg daily
2 weeks	Absent	Present	Absent	25mg/qd	Same as above
4 weeks	Absent	Absent	Absent	20mg/qd	Same as above
8 weeks	Absent	Absent	Absent	20mg/qd	Same as above
12 weeks	Absent	Absent	Absent	20mg/qd	Same as above
16 weeks	Absent	Absent	Absent	15mg/qd	Same as above
20 weeks	Absent	Absent	Absent	15mg/qd	Same as above
24 weeks	Absent	Absent	Absent	15mg/qd	Same as above
28 weeks	Absent	Absent	Absent	7.5mg/qd	Same as above
32 weeks	Absent	Absent	Absent	7.5mg/qd	Same as above
36 weeks	Absent	Absent	Absent	7.5mg/qd	Same as above
40 weeks	Absent	Absent	Absent	7.5mg/qd	Same as above
44 weeks	Absent	Absent	Absent	7.5 mg/5 mg alternating	Same as above
48 weeks	Absent	Absent	Absent	7.5 mg/5 mg alternating	Same as above
52 weeks	Absent	Absent	Absent	7.5 mg/5 mg alternating	TCM; mycophenolate mofetil 0.5 g morning, 0.5 g evening; hydroxychloroquine 50 mg twice daily; fosinopril 10 mg daily

Belimumab is a recombinant human IgG-1λ monoclonal antibody that inhibits B-cell activating factor, thereby modulating abnormal B-cell activity in SLE. It was the first biologic agent approved for the treatment of active SLE in 2011. Although global approval for its use in LN remains limited, accumulating clinical evidence has demonstrated favorable outcomes in patients with LN receiving belimumab. These outcomes include significant reductions in proteinuria, decreased disease relapse rates, and more rapid tapering of glucocorticoids, which collectively contribute to reduced medication-related toxicity and prevention of long-term organ damage. Early initiation of belimumab has been associated with increased likelihood of achieving renal remission and earlier disease control in LN management.⁸

An observational study involving patients with LN treated with belimumab reported an annual relapse rate of 1.7%, and 70% of patients with baseline 24-hour urinary protein excretion exceeding 1 g achieved renal remission.⁹ A systematic review and meta-analysis conducted by Han et al, with a mean observation period of 68 weeks, showed that patients receiving belimumab had a lower risk of renal relapse, deterioration of renal function, or progression to end-stage renal disease compared to those receiving conventional therapy. The incidence of serious adverse events was also lower in the belimumab group.¹⁰

Furthermore, a two-year international randomized controlled trial involving 448 patients with LN demonstrated that the combination of belimumab with standard therapy significantly enhanced renal response. Patients in the belimumab group exhibited approximately 50% lower risk of renal-related events compared to those receiving standard therapy alone.¹¹ Collectively, these findings support the efficacy and safety of belimumab as an adjunctive treatment in the management of LN.

In addition to standard therapy, this pediatric patient received an oral, syndrome-differentiated TCM formula. According to TCM theory, the fundamental pathogenesis involves kidney qi deficiency, while the clinical manifestation arises from meridian obstruction due to blood stasis and pathogenic toxins, with warm toxin playing a persistent role in disease progression.¹² The etiology reflects a combination of internal and external factors. Internally, deficiency of vital qi results in impaired functioning of the zang-fu organs. Externally, an excess of pathogenic factors, such as heat-toxin and wind-damp-heat, invade the body and contribute to disease development.¹³

At the time of consultation, this patient presented with symptoms including dry mouth, chapped lips, and oral mucosal ulceration. These were attributed to spleen-kidney deficiency. Based on the four diagnostic methods of TCM, the

patient was diagnosed with the Yin-Yang Toxin pattern, characterized by a syndrome of spleen-kidney dual deficiency complicated by internal retention of damp-heat. During the disease relapse stage, a modified formulation of Ganlu Xiaodu Dan combined with Fengsui Dan was prescribed. The treatment followed the principle of addressing the manifestation during the acute phase, with a primary focus on eliminating damp-pathogen. Ganlu Xiaodu Dan was selected for its properties of clearing heat, detoxifying, and promoting diuresis to resolve turbidity. Fengsui Dan was used to nourish kidney water, ascend yang, fortify qi, and suppress fire to reduce emissions. The combination addressed both the manifestation and the root cause of the disease.

After 14 doses, mucosal ulcers resolved, and symptoms such as fever, dry mouth, halitosis, abdominal pain, and bloating were no longer present. Hematuria showed significant improvement, indicating successful clearance of damp-heat. However, the patient continued to exhibit a dull complexion, red tongue, and recurrent respiratory tract infections. At this stage, the excess pathogenic factors had subsided, revealing an underlying deficiency of qi and blood in the lung, spleen, and kidney systems. Consequently, the treatment strategy was adjusted to a formula based on Liuwei Dihuang Wan, aimed at nourishing yin and tonifying the kidney. Given the persistence of blood stasis and pathogenic toxins throughout the disease course, additional herbs were incorporated to invigorate blood and resolve stasis.

Following administration of the revised formula, a significant reduction in the frequency and severity of respiratory infections was observed. Infections that did occur were mild and resolved promptly. The complexion of the patient became lustrous, the tongue color returned to a healthy red, and the pulse was calm and moderate. These clinical outcomes suggest that syndrome-differentiated TCM therapy may be effective in alleviating systemic manifestations of pediatric LN and in regulating underlying constitutional imbalances.

This case employed an integrative therapeutic approach combining TCM with conventional Western medical treatment, which resulted in rapid and effective control of clinical manifestations, including hematuria, proteinuria, and SLE disease activity. This outcome reflects the potential advantages of a combined treatment strategy in achieving satisfactory clinical efficacy.

Contemporary pharmacological research has indicated that TCM may enhance the therapeutic effectiveness of conventional pharmacotherapy while reducing adverse effects associated with long-term use of glucocorticoids and immunosuppressants. Reported benefits include mitigation of secondary hypertension, hyperglycemia, increased susceptibility to infection, and growth and developmental impairments. TCM may also reduce the risk of symptom rebound following tapering or discontinuation of corticosteroids.¹⁴

A large-scale clinical study conducted by Li et al, which included 1,002 patients with LN, demonstrated that the TCM formula Shenqi Dihuang Tang enhanced the therapeutic efficacy of concurrent treatments, improved psychological well-being, and reduced antagonistic reactions to immunosuppressants. These findings support the notion that integration of TCM with Western medicine can yield superior clinical outcomes.¹⁵

According to a recent state-of-the-art review by Chan et al³ children with LN demonstrate more active serology, higher relapse rates and greater corticosteroid toxicity than adults, supporting the use of steroid-sparing regimens and prolonged maintenance (≥ 5 years). Their analysis also underscores the paucity of randomised data for belimumab in active paediatric LN and recommends systematic screening for monogenic SLE in patients with disease onset < 10 years, hypocomplementaemia or refractory course—criteria that fit our patient and highlight the need for definitive genetic work-up in future reports.

It is worth noting that anti-dsDNA antibody is specific antibodies for SLE and is closely related to LN.² However, the reported positivity rate ranges from 60% to 70%, indicating that not all patients with LN exhibit detectable levels of anti-dsDNA antibody. In this case, the child presented initially with gross hematuria, without typical clinical manifestations such as malar rash, joint pain, or alopecia. The negative result for anti-dsDNA antibody may therefore be attributed to the atypical and limited clinical presentation.

Furthermore, multiple experimental studies have demonstrated that Chinese medicinal herbs such as *Radix Astragali* and *Rehmanniae Radix* praeparata exert nephroprotective effects by attenuating renal histopathological damage, reducing interstitial fibrosis, and limiting renal tubular injury.¹⁶ However, given that she was already undergoing standard immunosuppressive therapy (corticosteroids combined with mycophenolate mofetil) and B-cell-targeted therapy (belimumab), the additional contribution of TCM remains uncertain.

Conclusion

A single case report demonstrated that the combination of belimumab and individualized TCM may safely and effectively control refractory childhood LN, reduce corticosteroid dosage, and sustain remission; however, validation through studies with larger sample sizes is required.

Abbreviations

LN, lupus nephritis; SLE, systemic lupus erythematosus; Fb, Fibrinoid body; SLEDAI, Systemic Lupus Erythematosus Disease Activity Index.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Ethics Approval and Consent to Participate

This study was conducted with approval from the Ethics Committee of Hubei Provincial Hospital of Traditional Chinese Medicine. This study was conducted in accordance with the declaration of Helsinki. Written informed consent was obtained from the patient's legal guardian. Institutional approval was not required for the publication of the case details.

Consent for Publication

The patient's legal guardian signed a document of consent for publication.

Acknowledgments

We would like to acknowledge the hard and dedicated work of all the staff who implemented the intervention and evaluation components of the study.

Author Contributions

Lihua Deng: Writing – review and editing, Resources, Methodology.

Lin Guo: Formal analysis, Data curation.

Zhuoting Tang: Project administration, Visualization.

Kefei Xu: Writing - original draft, Resource, Writing - review and editing.

All authors took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

No external funding has been received for conducting the study.

Disclosure

The authors declare that they have no competing interests.

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