

Clinical Progress of Integrated Traditional Chinese and Western Medicine in the Treatment of Refractory Nephrotic Syndrome in Children

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Abstract:

Pediatric refractory nephrotic syndrome is a therapeutic challenge in pediatric kidney diseases, characterized by insensitivity, dependence or frequent recurrence to hormone treatment. In recent years, the combination of traditional Chinese and Western medicine in the treatment of pediatric refractory nephrotic syndrome has demonstrated unique advantages. This article systematically reviews the clinical progress of the treatment of RNS in children with both traditional Chinese and Western medicine, including the current status and challenges of Western medicine treatment, the etiology, pathogenesis and syndrome differentiation of traditional Chinese medicine, clinical research on the combination of traditional Chinese and Western medicine treatment, and the experience of famous and senior traditional Chinese medicine practitioners. Clinical studies have shown that the combination of traditional Chinese medicine and standard Western medicine treatment can significantly reduce urinary protein, improve plasma albumin, regulate blood lipids, reduce hormone side effects, lower recurrence rates, and improve clinical efficacy. In the future, high-quality clinical research needs to be further conducted to explore the optimized treatment plan and mechanism of action of the combination of traditional Chinese and Western medicine.

Keywords:

Refractory Nephrotic Syndrome in Children, Integrated Traditional Chinese and Western Medicine, Biologics, Traditional Chinese Medicine, Clinical Progress

1. Introduction

Refractory childhood nephrotic syndrome is a condition that occurs in about 50% of primary nephrotic syndrome cases during the course of the disease, characterized by frequent relapses, steroid dependence or steroid resistance. Its pathophysiological mechanism is complex and involves immune disorders, podocyte damage, genetic factors, and other aspects. Modern medicine mainly employs treatments such as

glucocorticoids, immunosuppressants (such as tacrolimus, cyclophosphamide), and biological agents (such as rituximab, omalizumab), but there are issues such as high costs.

Traditional Chinese medicine has accumulated rich experience in the prevention and treatment of RNS in children. Through holistic regulation and syndrome differentiation and treatment, it has unique advantages in alleviating clinical symptoms, reducing the side effects of hormones, and preventing recurrence [1]. In recent years, with the deepening of research on the integration of traditional and Western medicine, a series of clinical studies and experience summaries have provided new ideas and methods for the treatment of RNS in children. This article aims to review the clinical progress of traditional and Western medicine in the treatment of RNS in children, providing references for clinical practice and research.

2. Western Medicine Treatment

The main strategies for treating pediatric RNS with Western medicine include hormone therapy, immunosuppressive therapy and biological therapy. Hormone therapy usually employs glucocorticoids such as prednisone, but long-term and high-dose use can lead to side effects such as growth retardation, obesity, and osteoporosis [2]. For patients who are hormone-dependent, the “tailing-off therapy” (gradually reducing the dosage) can easily lead to recurrent attacks. Immunosuppressants such as cyclophosphamide, tacrolimus, cyclosporine A, and mycophenolate mofetil can be used as adjunctive or alternative treatments for hormones. The combination of cyclophosphamide and rituximab in the treatment of children with refractory nephrotic syndrome can achieve better clinical efficacy, effectively improving the renal function and immune function levels of the children, and helping to improve their prognosis. At the same time, it does not significantly increase adverse reactions [3]. Tacrolimus inhibits calcineurin and blocks T-cell activation, and the combination of tacrolimus with prednisone has a better effect in treating refractory nephrotic syndrome, improving serum creatinine, serum albumin, and 24-hour urine protein quantification indicators, and reducing adverse reactions [4]. However, its nephrotoxicity and long-term efficacy are still limited. Cyclosporine A has a significant therapeutic effect on children with refractory nephrotic syndrome, and its immunosuppressive effect can significantly reduce systemic inflammatory responses. In non-immunosuppressive aspects, it can reduce renal blood flow, lower glomerular filtration pressure, and improve proteinuria [5]. MMF has no nephrotoxicity and has the characteristic of less toxic adverse reactions, which has a certain role in improving the treatment effect of children with SRNS. The short-term adverse reactions of MMF are less than those of other immunosuppressants such as cyclophosphamide and cyclosporine A, and common adverse reactions include diarrhea, combined infection, and fever, etc. [6] Leflunomide is a potent immunosuppressant, which can effectively reduce the activity of dihydroxyacid dehydrogenase, block lymphocyte proliferation, and inhibit the immune inflammatory response of the body. It is often used to treat rheumatoid arthritis, kidney transplant rejection reactions, and RNS [7].

Biological agents such as rituximab, as a B-cell depleting agent targeting CD20, significantly reduce the recurrence rate of hormone-dependent/frequent relapsing NS by eliminating abnormal B cells, regulating T cell subsets, and protecting podocytes. It also reduces the dosage of glucocorticoids [8]. The evidence-based guidelines for the diagnosis and treatment of pediatric steroid-dependent NS/frequent relapsing NS in China state that RTX can effectively induce remission, reduce recurrence, has better

efficacy when combined with other immunosuppressants, has fewer adverse reactions, and has broad application prospects in these two types of patients. The Chinese drug guidelines recommend a dosage of 375 mg/m² once a week for 1 to 4 times [9]. However, its high price limits its clinical application. Oportumab is a new humanized anti-CD20 monoclonal antibody approved by the National Medical Products Administration in 2021. Currently, its approved indications in China are for combination with chemotherapy for adult patients with stage II follicular lymphoma accompanied by large masses, stage III or IV follicular lymphoma, and who are initially treated. Compared with rituximab, Oportumab is believed to potentially play a better role in the treatment of immune-mediated kidney diseases due to its stronger B-cell clearance ability and more persistent effect [10]. Afotumab is a second-generation fully humanized anti-CD20 monoclonal antibody. In December 2021, the National Medical Products Administration approved its import registration application for the treatment of adult relapsing multiple sclerosis, making it a rare disease medication. Studies have shown that compared with rituximab, it significantly reduces immunogenicity, which gives it potential advantages in treating RNS children who are intolerant or resistant to rituximab.

3. Traditional Chinese Medicine's Causes of Disease and Pathogenesis as Well as Diagnosis and Classification Methods

3.1. Understanding of the Causes and Mechanisms of the Disease

In traditional Chinese medicine classics, there is no term “nephrotic syndrome”. Based on its clinical manifestations, it is mostly classified under categories such as “edema”, “urinary turbidity”, and “deficiency of vital energy”. Traditional Chinese medicine holds that children have “fragile internal organs and undeveloped physique”, and the deficiency of the lung, spleen, and kidney is the intrinsic basis of this disease. External pathogen invasion, internal retention of water and dampness, and obstruction of blood vessels by stasis are important links in the occurrence and development of the disease. Spleen deficiency and dampness retention are the core pathogenesis of this disease. The spleen governs the transformation and transportation of water and dampness; when the spleen is deficient, water and dampness accumulate internally and overflow onto the skin, causing edema; when the spleen fails to raise clear qi, proteinuria occurs. Liu Chunying attaches great importance to the roles of “wind, deficiency, stasis, dampness, and heat” in the evolution of the disease course of children with RNS, with “deficiency” being more inclined to the lung in the early and remission stages, and more focused on the spleen and kidney in the later stage. In addition, during the remission stage, prevention of external pathogen invasion is emphasized, and in the course of the disease, prevention and treatment of blood stasis are given priority [11]. Professor Sun Yixiu believes that the onset of childhood RNS is caused by both internal and external factors. The spleen disperses upward the essence to the lung and downward to the kidney and bladder for transportation. The internal factor of spleen deficiency is the key to the onset of the disease; dampness is sticky and obstructs the yang of the spleen, causing water and dampness to accumulate and intensify, leading to repeated and prolonged illness that is difficult to recover. The external factor of damp heat is the main factor for the recurrence and persistence of the disease [12].

3.2. Differential Diagnosis Classification

At present, scholars have not reached a unified understanding on the diagnosis and treatment of RNS. The diagnosis is divided into deficiency and excess conditions, and combined with the causes and pathogenesis of RNS, the clinical classification mainly includes spleen-kidney yang deficiency type, stasis blood internal obstruction type, damp-heat internal accumulation type, qi-yin deficiency type, and yin deficiency with excessive fire type. Liu Mengling [13] et al. classified the manifestations of RNS children into positive qi deficiency, wind pathogen invading meridians, damp-heat adhering to meridians, stasis blood blocking meridians, etc. types, believing that the formation of stasis blood is a common result in the development and prolongation of this disease, and tangible stasis and intangible stasis jointly affect microcirculation, causing kidney function damage and dysfunction. Sun Tingting [14] et al. classified RNS children into three types for treatment: spleen-kidney yang deficiency type, stasis blood internal obstruction type, and damp-heat internal accumulation type. The total effective rate of treatment was 86.70%, and the incidence of adverse reactions was significantly lower than that of the control group. If hormones are used for long-term and large-scale treatment, it will consume the body's positive qi and yin fluids. First, it will cause symptoms of qi-yin deficiency. If the condition further prolongs, it is likely to develop into yin deficiency with excessive fire, presenting symptoms related to virtual heat. Li Xinmin [15] et al. divided RNS children into three stages: acute recurrence stage, disease progression stage, and disease remission stage. Different treatment methods were adopted in each stage, and it was emphasized that the treatment of pediatric RNS should use moderate and gentle drugs. Chuanlu, caogou, fuzi, and huanglian, although all can remove dampness, are suitable for children with tender internal organs and thin intestines and stomachs. Long-term use will definitely damage the spleen and stomach, leading to sudden complications. Hormone treatment combined with immunosuppressants or biological agents is the fundamental approach. Combined with the intervention of traditional Chinese medicine based on the classification and diagnosis of syndrome, it can not only significantly improve clinical efficacy but also reduce the risk of adverse reactions, and has clinical promotion significance. By integrating the treatment ideas of staged and classified therapy, accurately diagnose based on the urgency and slowness of each stage of hormone treatment, and effectively alleviate the discomfort of children.

4. Experience of Renowned Traditional Chinese Medicine Practitioners

Many physicians, when treating children with RNS, adopt a syndrome-based approach, integrating classic formula theories with modern pharmacology theories, and formulating their own empirical formulas. Professor Li Xinmin [16] based on the clinical characteristics of children with RNS and the characteristics of children's constitution, and according to years of clinical practice, focused on the key pathological mechanism of "improper circulation of qi in the triple burner", advocating for the regulation and promotion of the qi circulation in the triple burner, especially strengthening the spleen and stomach in the middle burner. And according to different stages, different treatment methods were adopted, such as clearing and promoting the lung qi in the upper burner, regulating and promoting the spleen and stomach in the middle burner, and regulating and promoting the qi circulation in the lesser yang. Professor Wang Xuefeng [17] believed that the pathogenesis of hormone-dependent nephropathy and recurrent nephropathy is mainly "excessive heat consuming qi", and the key point of this disease treatment is to maintain the function

of generating less heat and generating qi, reducing the side effects of “excessive heat consuming qi”, thereby preventing hormone dependence and frequent recurrence. At the same time, it was pointed out that patients with refractory nephropathy combined with atopic dermatitis are different from ordinary sores and boils. This is due to the accumulation of yin deficiency and toxins, weakness of the body, and the toxins have not been eliminated after the dampness has accumulated, thus causing the yin to be damaged and the disease difficult to be cured. In treatment, it emphasizes prescribing based on the different stages of nephropathy, and at the same time, emphasizes nourishing qi and yin. Professor Ding Ying [18] pointed out that the liver and kidney yin deficiency combined with wind-blood stasis is more common in children with a constitution of yin deficiency, excessive use of warm-dry medicines, or excessive diuresis. It is particularly seen in children who have used hormones for a long time and in large quantities. In the Ren Disease Formula No.3, rehmannia is used to nourish the kidney yin and increase the essence and blood, mountain yam is used to nourish yin and balance the triple burner, wine-processed cinnamon is used to nourish the liver yin, polyporus is used to gently drain the dampness of the spleen, danpi is used to clear and purge liver fire, and qishu, huangbai are used to nourish yin and reduce false fire. Together, these drugs can achieve the effect of nourishing the liver and kidney and promoting lung qi and clearing heat. Master Zheng Xin [19] emphasized the importance of addressing both the deficiency and the manifestation, particularly emphasizing the lung and kidney, as well as the balance of yin and yang. During the treatment process, it emphasizes strengthening the body's defenses and eliminating pathogenic factors, harmonizing yin and yang, and at the same time, distinguishing the pathogenic factors, promoting blood circulation and eliminating stasis throughout the process. Professor Liu Chunying [20] believed that lung, spleen, and kidney deficiency is the basic disease mechanism, and phlegm-stasis and blood stasis are the pathological basis. In clinical practice, it emphasizes treating the three organs of lung, spleen, and kidney together, especially emphasizing the supplementation of lung qi to prevent external invasion. It often uses the modified Yubeixing Powder, and at the same time, throughout the treatment process, it also focuses on promoting blood circulation and eliminating stasis. Through syndrome-based treatment, it can alleviate the symptoms of excessive heat and yin deficiency caused by glucocorticoid hormones, and calcined dragon bone and calcined oyster are used to nourish yin and retain sweat, and honeysuckle, chrysanthemum, and asarum are used to clear and purge lung heat and relieve cough. The combination of these drugs can achieve the effect of nourishing the liver and kidney and promoting lung qi and clearing heat. Master Zheng Xin emphasized that the treatment should be individualized, adjusting the duration and dosage of hormone and immunosuppressant use based on individual differences to reduce the recurrence rate of RNS and lower the side effects of glucocorticoid hormones and immunosuppressants.

5. Progress in Integrative Medicine Treatment

In recent years, numerous clinical studies have confirmed the superiority of the combined treatment of traditional Chinese and Western medicine for pediatric RNS. Ni Jinyu et al. [21] found that the application of traditional Chinese medicine combined with hormone non-tailing therapy in the treatment of pediatric RNS could reduce urinary protein, increase plasma albumin, lower blood lipids, improve TCM syndromes, improve quality of life, and enhance clinical efficacy. At the same time, the Qi-enhancing, Blood-activating and Heat-clearing Formula [22] sequenced and symptomatic treatment for children with refractory nephrotic syndrome could reduce

urinary protein, increase ALB, lower blood lipids, improve hypercoagulation state, and better improve the quality of life of children. The Qi-enhancing, Kidney-strengthening and Activating Blood Decoction [23] in the treatment of pediatric RNS has significant clinical efficacy and TCM syndrome efficacy, can significantly reduce the levels of 24 h UTP, Scr, BUN, TNF- α , TGF- β 1, IL-6, IL-17, Fib and TCM syndrome score of children, and increase the level of ALB. On the basis of hormone combined with tacrolimus treatment, Zhibai Dihuang Pills combined with Wuling San modification [24] as an auxiliary treatment for children with RNS of liver and kidney yin deficiency syndrome can reduce urinary protein, improve lipid metabolism disorder and hypercoagulation state, and can regulate immune inflammatory response, and has comprehensive efficacy and TCM syndrome efficacy. Baonian Xiaozhuo Decoction [25] in the treatment of pediatric refractory nephrotic syndrome has definite efficacy, can improve the renal function of children, and has good safety. The efficacy and safety of Baishilong Decoction combined with multi-target therapy in the treatment of pediatric refractory nephrotic syndrome were observed [26]. After treatment, there were statistically significant differences in 24 h urinary protein quantification, plasma albumin, endogenous creatinine clearance rate, total cholesterol levels between the two groups and before and after treatment in the same group ($P < 0.05$). The total effective rate of clinical efficacy in the control group was 68.8%, and that in the treatment group was 84.4%, with the incidence of adverse reactions being 18.8% and 9.3% respectively, and the differences were statistically significant ($P < 0.05$). The efficacy and safety of Baishilong Decoction combined with multi-target therapy in the treatment of pediatric refractory nephrotic syndrome with hormone maintenance stage were significant, with high safety and low toxic side effects. The study of the efficacy and clinical efficacy of the Qi-enhancing, Kidney-strengthening, Activating Blood and Circulating Meridian Method [27] combined with hormone in the treatment of children with hormone-dependent refractory nephrotic syndrome at the hormone maintenance stage found that RNS children were randomly divided into 2 groups. The treatment group of 25 cases was treated with the Qi-enhancing, Kidney-strengthening, Activating Blood and Circulating Meridian Chinese medicine on the basis of hormone treatment, while the control group of 25 cases was treated with simple hormone therapy. The comparison of total effective rates between the two groups showed a statistically significant difference ($P < 0.05$), and the efficacy of the treatment group was better than that of the control group. The Qi-enhancing, Kidney-strengthening, Activating Blood and Circulating Meridian Method combined with hormone in the treatment of children with hormone-dependent RNS at the hormone maintenance stage can significantly alleviate clinical symptoms, reduce urinary protein, and lower the recurrence rate of the disease. Si Leiming [28] et al. conducted a systematic analysis of 30 clinical cases of children with refractory nephrotic syndrome, summarized the characteristics of their syndromes, verified the pathological mechanism of “heat, toxin, and blood stasis” mutual obstruction, and “heat, toxin, and blood stasis” mutual obstruction is an important pathological change of this disease, with a total effective rate of 93.33%. Li Yanyu [29] et al. believe that in the later stage of the disease, when the hormone is reduced to a small amount (prednisone < 0.25 mg·kg⁻¹), this prescription is generally not easily used. However, it is not an absolute contraindication. If the child does not have obvious yang deficiency syndrome and there is indeed the syndrome of Mahuanglianqiaozhongdou Decoction, it can be treated according to the syndrome, with modifications as needed. Children with weak yang should not use Mahuanglianqiaozhongdou Decoction. The age of onset, serum albumin and triglycerides have significant diagnostic value for the hormone resistance

and frequent recurrence of RNS children. The clinical efficacy of Renkong intervention in children with refractory nephrotic syndrome believes that serum cholesterol has significant diagnostic value for the hormone resistance of RNS children; serum total protein also has significant diagnostic value for the frequent recurrence of RNS children. Renkong can relieve the clinical symptoms of RNS children, increase serum cortisol levels, and protect adrenal cortical function.

6. Discussion and Conclusions

Pediatric refractory nephrotic syndrome is a complex disease with a prolonged course and difficult to cure completely. Treatment with simple Western medicine hormones or combined with immunosuppressants often fails to be effective and the condition is prone to deteriorate; moreover, due to the incomplete development of children's internal organs and their weaker immunity, the disease is even more harmful. Long-term use of hormones will also increase the burden on the liver and kidneys and induce kidney damage or even renal failure. On the basis of conventional Western medicine hormone and immunosuppressant treatment, the use of traditional Chinese medicine can significantly improve the therapeutic effect, control the progression of the disease, improve the prognosis and alleviate the suffering of children. Thus, it can be seen that the treatment of pediatric RNS with traditional Chinese medicine not only has definite efficacy and high safety, but also can make up for the single nature of Western medicine. The treatment plan can be customized based on individual differences of children, achieving individualized treatment. At the same time, it can reduce the adverse reactions of long-term use of glucocorticoids (GC). In summary, the combination of traditional and Western medicine treatment takes advantage of the strengths of both, forming a complementary treatment model. Modern medicine has an advantage in quickly controlling symptoms, while traditional Chinese medicine has unique effects in overall regulation, reducing the side effects of hormones, and preventing recurrence.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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