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Efficacy and Safety of High-Dose versus Low-dose methylprednisolone pulse therapy for IgA vasculitis Nephritis: a retrospective observational study

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Abstract

Objective: To investigate the clinical efficacy and safety of two different dosage of methylprednisolone pulse therapy in children with IgAVN presenting with crescent formation involving less than 50% of glomeruli.

Methods: Based on the glucocorticoid dosage, 122 pediatric patients diagnosed with IgAVN were divided into high-dose group and low-dose(reduced-dose/mini-dose) group. Clinical efficacy, immunological parameters, and incidences of adverse reactions were compared.

Results: At 1 and 3 months, the CR rates of high-dose group and low-dose group were 9.2% vs 0.0% and 44.7% vs 26.1%, respectively, with statistically significant differences($P<0.05$). At 6 and 12 months, the CR rates were 71.1% vs 67.4% and 93.4% vs 93.5%, showing no statistically significant differences respectively($P>0.05$). The ORR at 1 and 3 months were 70.4% vs 32.4% and 85.5% vs 54.3%. At 6 and 12 months, the ORR were 93.4% vs 91.3% and 97.4% vs 97.8%, with no significant differences respectively. In both groups, 24h UTP and URBC decreased significantly, while serum albumin levels increased markedly at all post-treatment time compared with baseline. Intergroup differences were statistically significant at 1 and 3 months but not at 6 and 12 months. The incidences of all adverse reactions were significantly higher in the high-dose group than low group.

Conclusion: The high-dose group demonstrated superior efficacy to the low group at 1 and 3 months after treatment, whereas comparable efficacy was observed at 6 and 12 months. The high-dose group showed significantly higher rates of infection and other adverse reactions compared with low group.

Keywords: IgA vasculitis nephritis; Low-dose(Mini-dose/Reduced-dose) Methylprednisolone pulse therapy; Adverse reactions; Efficacy

IgA vasculitis nephritis(IgAVN) is the most common and severe visceral complication^[1] of IgA vasculitis, representing the leading secondary glomerular disease in children and adolescents^[2-3]. Some adult patients may progress to chronic kidney disease or even end-stage renal failure, which significantly impairs renal function and imposes a substantial burden on healthcare systems. Clinical studies^[4] have demonstrated that the extent of renal injury is a core prognostic determinant in IgAVN patients. Persistent hematuria, proteinuria, and progressive decline in renal function are important features^[5] indicative of disease deterioration. Therefore, early, precise, safe, and effective individualized intervention is critical for improving long-term patient outcomes. Glucocorticoids(GC) constitute the first-line therapeutic agents. Current

domestic and international guidelines^[6-7] recommend the addition of GC for pediatric IgAVN patients with pathological grades IIb or IIIa accompanied by persistent proteinuria, nephrotic-range proteinuria, nephrotic syndrome, or pathological grades IIIb/IV. The 2016 Chinese HSPN guideline^[7] recommends that patients with severe clinical manifestations, diffuse pathological involvement, or crescent formation involving more than 50% of glomeruli should receive high-dose methylprednisolone(MP) pulse therapy. However, with the widespread clinical application, the limitations of high-dose MP pulse therapy have become increasingly apparent. Although it exerts robust anti-inflammatory effects^[8], its potent systemic immunosuppressive action predisposes patients to various adverse reactions^[9], including hypertension and infections, with particularly pronounced risks in the pediatric population. Some patients are compelled to discontinue treatment due to intolerance to drug-related toxicities, which adversely affects disease recovery and long-term prognosis. Furthermore, extensive clinical follow-up studies have revealed that the majority of patients with mild-to-moderate, non-critically ill IgAVN can achieve remission^[10] without the need for high-intensity GC pulse therapy. The high-dose regimen may thus represent overtreatment, entailing redundant efficacy and excessive risks. Such overtreatment not only fails to improve long-term outcomes but also substantially increases the incidence of adverse events and the financial burden on patients, which is inconsistent with the contemporary principles of precision medicine and individualized therapy. Moreover, the clinical phenotypes and pathological grades of pediatric IgAVN are not well correlated. The majority of cases exhibit crescent formation involving less than 50% of glomeruli^[11-12]; however, the most common clinical phenotypes are hematuria/proteinuria and nephrotic syndrome^[13], which often respond suboptimally to conventional-dose GC therapy. Although recent European guidelines(SHARE) and the 2025 KDIGO and IPNA guidelines^[6,14-18] have indicated that MP pulse therapy may also be considered as a first-line treatment for IgAVN with crescents involving less than 50% of glomeruli, and although previous literature^[19] has demonstrated the utility of MP pulse therapy in Henoch-Schönlein purpura nephritis with minor crescentic lesions, there remains no international or domestic consensus on the use of MP pulse therapy specifically for the aforementioned phenotypic subgroups.

Given the above circumstances, our center has conducted several tens of cases using a sub-pulse-dose GC induction regimen. We found that reducing the MP pulse dose to 4–6 mg/kg/day for three consecutive days, repeated over 2–3 courses, achieved comparable efficacy to the high-dose MP pulse regimen at 6 months, with a substantially lower incidence of adverse reactions. In our center, the dose range that is lower than the high-dose regimen(15-30 mg/kg/day) but higher than the conventional dose(1-2 mg/kg/day), while still meeting the definition of pulse therapy^[20], is designated as the "mini-dose"(4-6 mg/kg), also referring as reduced-dose or low-dose pulse MP in literature. The advantage of the mini-dose MP pulse therapy lies in its ability to preserve core anti-inflammatory efficacy while minimizing GC-related adverse effects^[21-26] and mitigating the risk of overtreatment, thereby meeting the therapeutic needs of the majority of patients with mild-to-moderate IgAVN and even some with pathological grade IIIb disease. Nevertheless, there is currently a paucity of domestic and international studies on mini-dose MP pulse therapy in IgAVN. The therapeutic equivalence and safety profile of the mini-dose regimen compared with the traditional high-dose MP pulse strategy remain to be elucidated. Critical scientific questions—including whether the mini-dose regimen can serve as a substitute for the high-dose regimen in the mainstream IgAVN patient

population, the optimal dosage for patients stratified by different disease severities, and the impact of dose adjustment on short-term remission rates and long-term prognosis—remain unresolved.

Subjects and Methods

I. Study Subjects

This study retrospectively analyzed a total of 122 pediatric patients who were hospitalized in the Department of Pediatric Nephrology, Rheumatology, and Immunology at the Affiliated Hospital of Xuzhou Medical University from May 2017 to May 2026, and were diagnosed with IgAVN confirmed by renal biopsy, all with ISKDC renal pathological grade III. Based on the therapeutic regimen, the patients were divided into a high-dose group (n=76) and a mini-dose group (n=46). The follow-up period extended until May 2026. Inclusion criteria: (1) Patients aged 3-18 years diagnosed with IgAVN presenting as the hematuria and proteinuria type or the nephrotic syndrome type; (2) All patients had ISKDC renal pathological grade III; (3) No prior treatment with GCs, immunosuppressants, or biological agents within 12 weeks before admission; (4) The guardians of the patients provided informed consent and agreed to participate in the study. Exclusion criteria: (1) Primary renal diseases such as glomerulonephritis or nephrotic syndrome causing hematuria and proteinuria; (2) Other secondary renal diseases, including lupus nephritis and diabetic nephropathy; (3) Severely incomplete medical records or poor compliance precluding the completion of subsequent follow-up.

II. Methods

1. Data Collection The last laboratory examination prior to renal biopsy was used as the study baseline. Clinical data of the patients were collected, and clinical efficacy parameters, immunological indices, infection-related indicators and the occurrence of other adverse reactions were recorded at 1, 3, 6, and 12 months after treatment. (1) General data: age, height, sex, body weight, and pathological classification; (2) Clinical efficacy parameters: 24-hour urinary protein excretion (24hUTP), urinary red blood cell count (URBC), serum albumin level and renal function; (3) Immunological parameters: CD4⁺T、CD8⁺T cell count and CD4⁺/CD8⁺T cell ratio; (4) Infection rate: number of infection cases and types of infection; (5) Incidence of other adverse reactions: hepatic injury, hyperlipidemia, hyperglycemia, hypertension and ocular hypertension; (6) Follow-up outcomes: prognostic grade assessment and relapse rate.

2. Treatment Protocol All patients received a basic therapeutic regimen consisting of GCs combined with mycophenolate mofetil (MMF) and conventional symptomatic medications^[7,27]. High-dose group: MP was administered at a dose of 20 mg/kg/day (maximum dose ≤ 1.0g/day) by intravenous infusion (iv) for 3 consecutive days as one course. A total of 2 courses were given at an interval of 1 week. During the interval between pulse therapy, oral prednisone acetate was given at 2 mg/kg/day (maximum dose ≤ 60 mg/day). After the completion of pulse therapy, sequential oral treatment with full-dose prednisone acetate was administered, followed by dose tapering after 4 consecutive weeks. The total courses was 9-12 months^[7]. Mini-dose group: MP was administered at a dose of 6 mg/kg/day (maximum dose ≤ 500 mg/day). The administration method and sequential treatment regimen were identical to those of the high-dose group.

3. Efficacy Evaluation (1) The remission rates and overall response rates (ORR) of the two groups at each

time point were calculated, and the distribution of complete remission(CR), marked remission(MR), partial remission()PR and no remission(NR) rates were compared between groups. (2)Changes in 24h UTP, URBC count, serum albumin and renal function parameters were compared between groups at each time point.

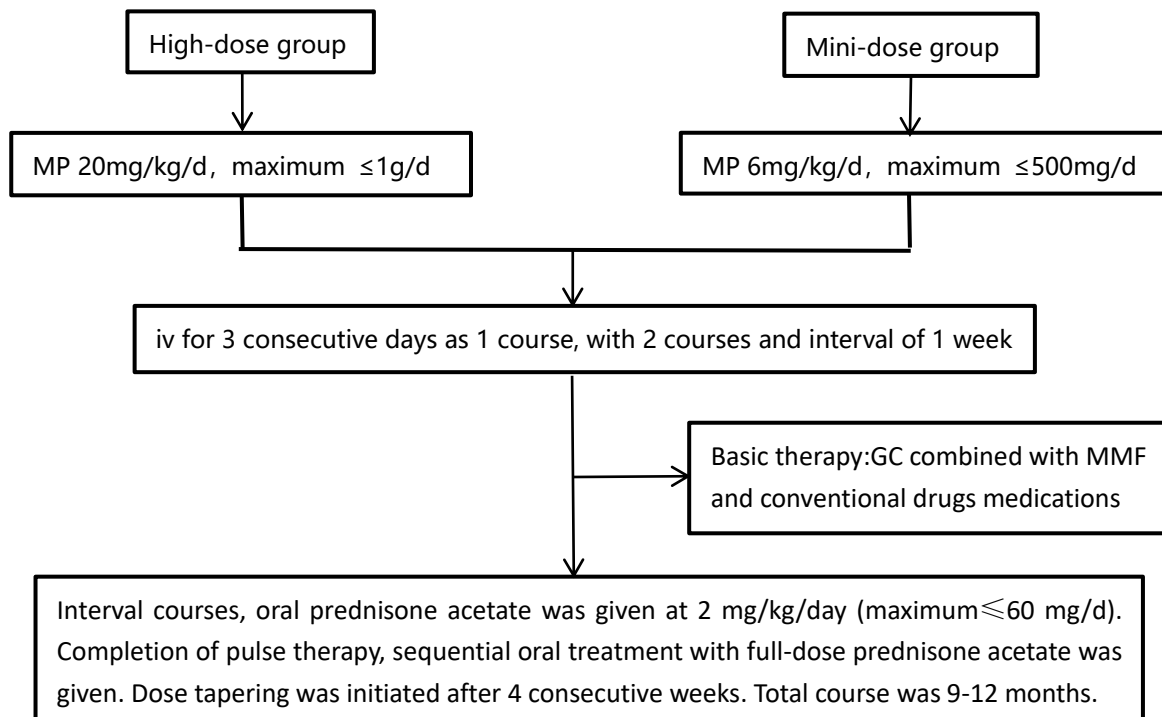


Figure 1 Treatment protocol diagram

4. Definitions

(1) Efficacy evaluation criteria^[28]: Complete remission(CR): Negative URBC, 24h UTP<0.2g and complete resolution of clinical manifestations and signs. Marked remission(MR): URBC count and 24hUTP decreased persistently by>50%, with near-complete resolution of clinical manifestations and signs. Partial remission(PR): URBC count and 24h UTP decreased by>25%, with marked improvement in clinical manifestations and signs. No response(NR): No improvement in clinical manifestations, signs or laboratory parameters. The overall response rate(ORR) was calculated as the sum of the CR, MR and PR rates.

(2) Prognostic evaluation: Prognosis was graded according to the criteria proposed by Counahan^[29] et al., categorized as grades A through D: Grade A(CR): Normal physical examination, urinalysis, and renal function, sustained for>3 months. Grade B(minor urinary abnormalities): Normal physical examination and renal function, with microscopic hematuria or proteinuria; 24h UTP<1 g or≤40 mg/kg/day; URBC<10/HPF; normal renal function. Grade C(active nephropathy): 24hUTP>1 g or>40 mg/kg/day; URBC>10/HPF; with or without hypertension; estimated glomerular filtration rate(eGFR)>60 mL/min/1.73 m². Grade D(renal insufficiency): Elevated blood urea nitrogen(BUN) or serum creatinine(Scr); eGFR<60 mL/min/1.73 m²; including end-stage renal disease, renal transplantation or death. Grades A and B were defined as indicating a favorable prognosis, while grades C and D were defined as indicating a poor prognosis.

(3) Estimated glomerular filtration rate(eGFR): The eGFR was calculated using the Schwartz formula^[30]: $eGFR = 0.413 \times \text{height(cm)} / \text{Scr(mg/dL)}$.

(4) Relapse^[7]: It was defined as the reappearance of gross hematuria after CR, or positive urinary protein on

qualitative urinalysis in 3 tests within 1 week, or 24hUTP>0.15g, or urinary protein-to-creatinine ratio(mg/mg)>0.2.

(5) Adverse event definitions: Hepatic injury^[31]: Alanine aminotransferase(ALT)/aspartate aminotransferase (AST)>3 times the upper limit of normal(ULN). Dyslipidemia: Total cholesterol>5.2 mmol/L or triglycerides>1.7 mmol/L^[32]. Hyperglycemia: Fasting blood glucose>7.0 mmol/L or random blood glucose>11.1 mmol/L^[33]. Ocular hypertension: Intraocular pressure>21 mmHg^[34]. Hypertension: Systolic or diastolic blood pressure above the 95th percentile for age and sex-matched children^[35].

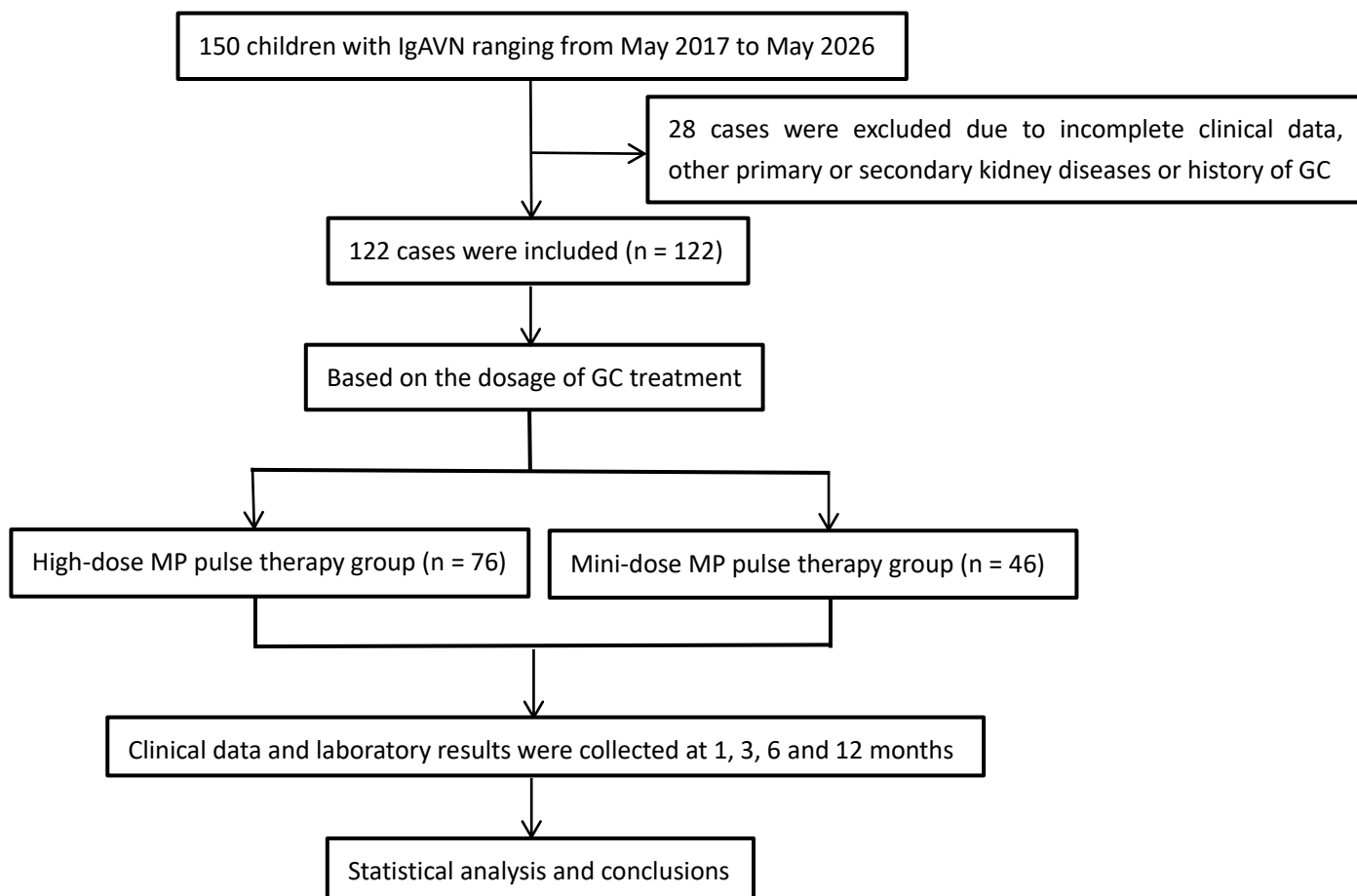


Figure 2 Study flow diagram

III. Statistical Analysis

Statistical analyses were performed using SPSS version 27.0 and Graphpad Prism version 11.0. Continuous data following a normal distribution were expressed as mean±standard deviation($\bar{x}\pm s$), and comparisons between the two groups were conducted using the independent samples t-test. Continuous data with a skewed distribution were expressed as median (interquartile range) [M(P₂₅, P₇₅)] and compared using the independent samples Mann–Whitney U test. Categorical data were expressed as frequencies (percentages)[n(%)] and analyzed using the chi-square test or Fisher's exact test, as appropriate. A two-sided P-value<0.05 was considered statistically significant for intergroup comparisons.

Results

I. Baseline Characteristics

The two groups were compared with respect to the following baseline parameters: age(years), sex

(male/female), height(cm), body weight(kg), 24hUTP(g), URBC count(cells/HPF), Scr(μ mol/L), BUN(mmol/L), eGFR(mL/min/1.73m²), serum albumin(g/L), fasting blood glucose(FBG)(mmol/L), systolic/diastolic blood pressure(SBP/DBP, mmHg), liver function(ALT/AST, U/L), serum lipids(TG/TC, mmol/L), intraocular pressure(IOP, mmHg), CD4⁺T cell count(cells/ μ L), CD8⁺T cell count(cells/ μ L) and CD4⁺/CD8⁺T cell ratio. No statistically significant differences were observed between the two groups in any of these parameters(all $P>0.05$), indicating that the baseline characteristics of the two groups were generally similar and comparable.

Table 1 Comparison of demographic and physiological data between two groups of pediatric patients with IgAVN[n(%), $\bar{x}\pm s$]

Indicator	High-dose group(n=76)	Mini-dose group(n=46)	χ^2/t	P
Sex/(case)			0.06	0.810
Male	33(43.42)	21(45.65)		
Famale	43(56.58)	25(54.35)		
Height/(cm)	150.49 $\pm$ 3.66	150.37 $\pm$ 3.57	0.17	0.863
Weight/(kg)	43.67 $\pm$ 3.96	42.28 $\pm$ 3.95	1.88	0.063
Age/(years old)	11.81 $\pm$ 1.85	11.51 $\pm$ 1.92	0.86	0.393
FBG/(mmol/L)	4.93 $\pm$ 0.42	4.85 $\pm$ 0.41	1.01	0.316
SBP/(mmHg)	113.43 $\pm$ 4.30	113.00 $\pm$ 4.10	0.55	0.583
DBP/(mmHg)	73.37 $\pm$ 5.02	72.22 $\pm$ 5.21	1.21	0.229
IOP/(mmHg)	13.83 $\pm$ 2.23	13.50 $\pm$ 2.17	0.80	0.426

Note: Continuous data with a normal distribution are expressed as mean $\pm$ standard deviation($\bar{x}\pm s$), and comparisons between the two groups were performed using the independent samples t-test. Categorical data are expressed as n(%), and comparisons were made using the chi-square test or Fisher's exact test. A P-value<0.05 was considered statistically significant for between-group differences.FBG: fasting blood glucose.SBP: systolic blood pressure.DBP: diastolic blood pressure.IOP: intraocular pressure.

Table 2 Comparison of kidney parameters between the two groups of pediatric patients with IgAVN[M(P₂₅,P₇₅),n(%), $\bar{x}\pm s$]

Indicator	High-dose group(n=60)	Mini-dose group(n=62)	t/Z/ χ^2	P
24h UTP/(g)	3.45 $\pm$ 0.35	3.57 $\pm$ 0.31	-1.79	0.076
URBC count/(cells/HP)	64.50(52.00,91.00)	60.00(53.00,77.25)	-0.40	0.688
Scr/(umol/L)	41.29 $\pm$ 2.60	41.80 $\pm$ 3.06	-0.99	0.324
BUN/(mmol/L)	4.21 $\pm$ 1.06	4.49 $\pm$ 0.96	-1.44	0.153
ALB/(g/L)	31.26 $\pm$ 6.02	31.70 $\pm$ 5.59	-0.40	0.688
eGFR(ml/min/1.73m ²)	133.55 $\pm$ 8.45	131.96 $\pm$ 9.39	0.97	0.335
Pathology/(case)			0.01	0.922
IIIa	34(44.74)	21(45.65)		
IIIb	42(55.26)	25(54.35)		

Note: Continuous data with a normal distribution are expressed as mean $\pm$ standard deviation($\bar{x}\pm s$), and comparisons between the two groups were performed using the independent samples t-test. Continuous data with a skewed distribution are expressed as median (interquartile range)[M(P₂₅, P₇₅)] and were compared using the independent samples rank-sum test(Mann-Whitney U test). Categorical data are expressed as n(%) and were compared using the chi-square test or Fisher's exact test. A P-value<0.05 was considered statistically significant for between-group differences.Scr: serum creatinine.BUN: blood urea nitrogen.ALB: serum albumin.eGFR: estimated glomerular filtration.

Table 3 Comparison of biochemical indicators between the two groups of pediatric patients with IgAVN($\bar{x}\pm s$)

Indicator	High-dose group(n=60)	Mini-dose group(n=62)	t	P
ALT(U/L)	14.80 $\pm$ 2.31	14.41 $\pm$ 2.32	0.90	0.369

AST(U/L)	19.80±3.02	19.33±3.01	0.85	0.399
TC(mmol/L)	4.35±0.55	4.22±0.57	1.23	0.221
TG(mmol/L)	1.15±0.22	1.09±0.24	1.40	0.164

Note: Continuous data with a normal distribution are expressed as mean±standard deviation($\bar{x}\pm s$), and comparisons between the two groups were performed using the independent samples t-test. A P-value<0.05 was considered statistically significant for between-group differences. ALT: alanine aminotransferase. AST: aspartate aminotransferase. TC: total cholesterol. TG: triglycerides.

Table 4 Comparison of lymphocyte subset parameters between the two groups of pediatric patients with IgAVN[M(P₂₅,P₇₅)]

Indicator	High-dose group(n=60)	Mini-dose group(n=62)	Z	P
CD4 ⁺ T(cells/ul)	571.50(396.75,673.75)	578.00(455.50,683.75)	-0.38	0.704
CD8 ⁺ T(cells/ul)	588.00(476.50,686.25)	622.50(530.25,677.25)	-0.77	0.439
CD4 ⁺ T/CD8 ⁺ T	0.96(0.73,1.23)	0.88(0.77,1.11)	-0.85	0.397

Note: Continuous data with a skewed distribution are expressed as median (interquartile range)[M(P₂₅, P₇₅)] and were compared using the independent samples rank-sum test (Mann-Whitney U test). A P-value<0.05 was considered statistically significant for between-group differences.

II. Clinical Efficacy

1.Remission rate After 1 month of treatment, there were statistically significant differences between the two groups in the rates of CR, MR, PR, NR and ORR(P<0.05). After 3 months, there were statistically significant differences between the two groups in the rates of CR, NR and ORR(P<0.05).After 6 and 12 months of treatment, there were no statistically significant differences between the two groups in the all rates(P>0.05). At 1 and 3 months of treatment, the CR rate and ORR in the high-dose group were significantly higher than those in the mini group. At 6 and 12 months of treatment, the CR rate and ORR in the two groups gradually became comparable.

Table 5 Comparison of treatment efficacy between the two groups of pediatric patients with IgAVN[n(%)]

Group	case	CR	MR	PR	NR	ORR(%)
1-month treatment						
High-dose group	76	7(9.2%)	28(36.8%)	20(26.3%)	21(27.6%)	72.4%
Mini-dose group	46	0(0.0%)	9(19.6%)	5(10.9%)	32(69.6%)	30.4%
χ^2		4.495	4.048	4.196	20.508	20.508
P		0.034	0.044	0.041	< 0.001	< 0.001
3-month treatment						
High-dose group	76	34(44.7%)	18(23.7%)	13(17.1%)	11(14.5%)	85.5%
Mini-dose group	46	12(26.1%)	9(19.6%)	4(8.7%)	21(45.7%)	54.3%
χ^2		4.243	0.282	1.690	14.396	14.396
P		0.039	0.595	0.194	< 0.001	< 0.001
6-month treatment						
High-dose group	76	54(71.1%)	10(13.2%)	7(9.2%)	5(6.6%)	93.4%
Mini-dose group	46	31(67.4%)	7(15.2%)	4(8.7%)	4(8.7%)	91.3%
χ^2		0.182	0.101	0.009	0.188	0.188
P		0.670	0.750	0.923	0.665	0.665
12-month treatment						
High-dose group	76	71(93.4%)	2(2.6%)	1(1.3%)	2(2.6%)	97.4%
Mini-dose group	46	43(93.5%)	1(2.2%)	1(2.2%)	1(2.2%)	97.8%
χ^2		0.000	0.025	0.131	0.025	0.025
P		0.990	0.874	0.718	0.874	0.874

Note: Categorical data are expressed as n(%) and were compared using the chi-square test or Fisher's exact test. A

P-value<0.05 was considered statistically significant for between-group differences.

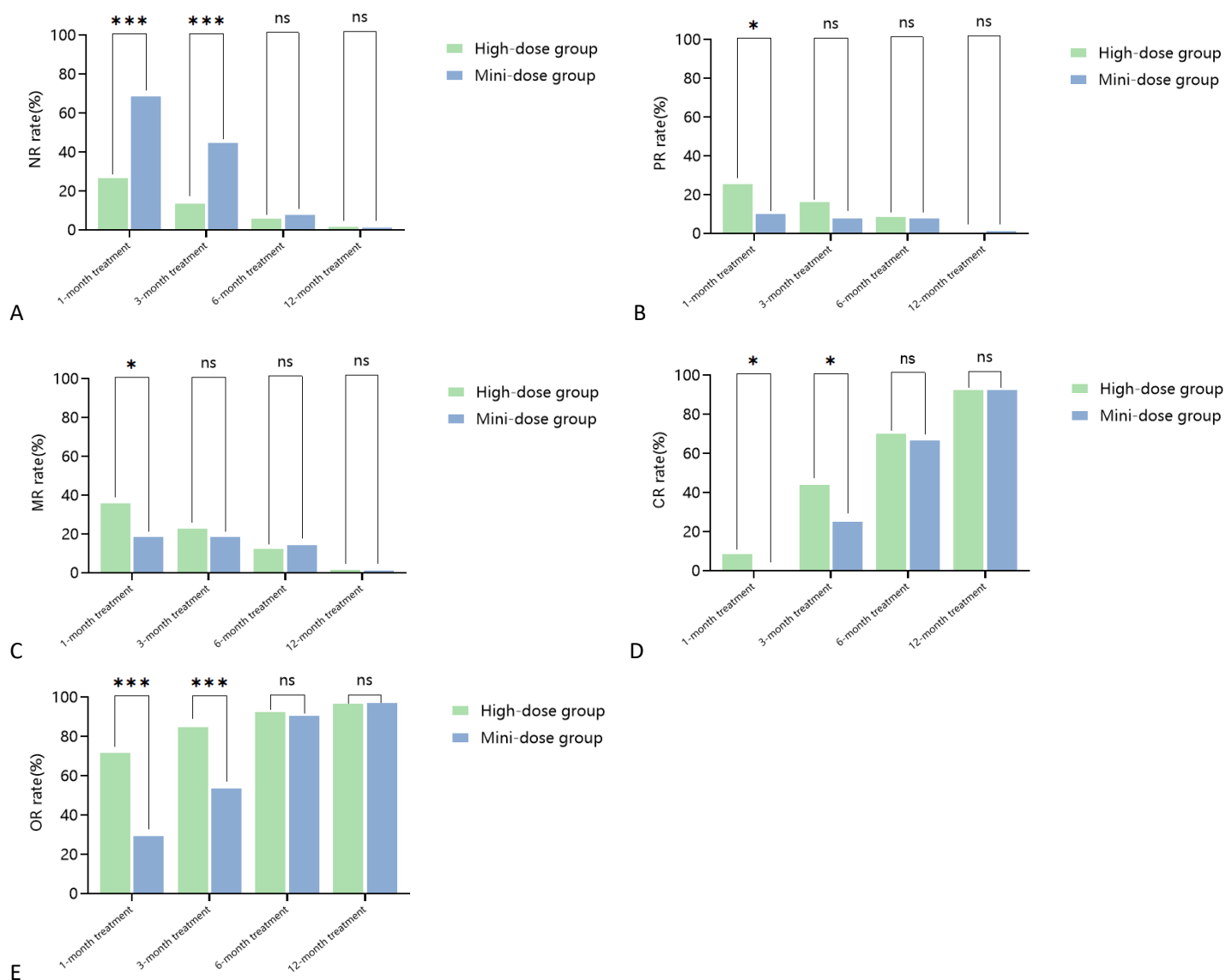


Figure 3 A-E Distribution of remission rates and ORR at different treatment time in the two groups of pediatric patients

2.Clinical symptoms and indicators

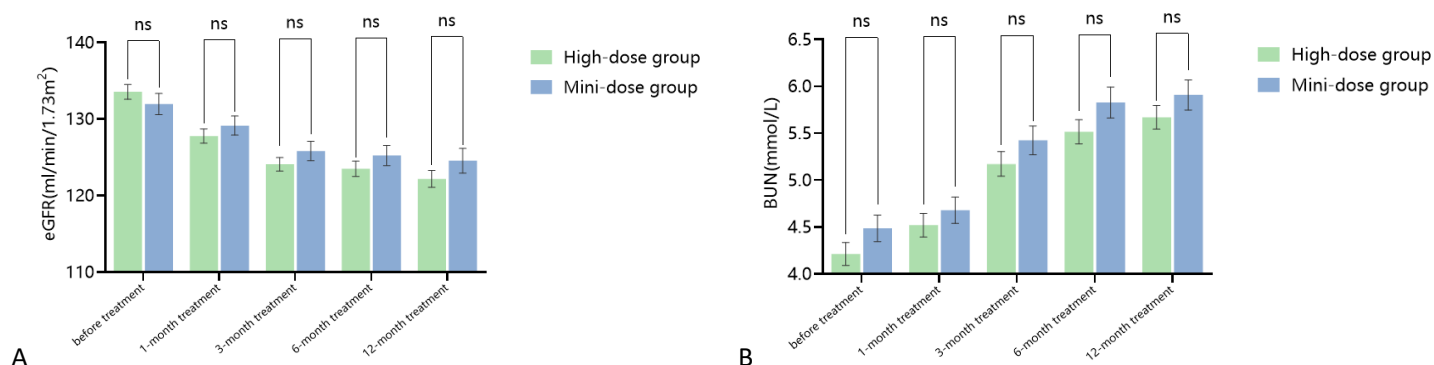
2.1 24h UTP and renal function In both groups after treatment, 24h UTP and URBC counts decreased significantly compared with baseline, gradually returning to levels consistent with renal CR; albumin levels increased significantly to normal ranges; Scr and BUN showed slight elevations after treatment; eGFR decreased after treatment but remained within the normal range, with no evidence of renal insufficiency. At baseline, both groups presented with proteinuria, hematuria, hypoalbuminemia and normal fluctuations in creatinine, BUN and eGFR, with no statistically significant differences between the groups($P>0.05$). At 1 and 3 months, the differences between groups in 24h UTP, albumin and URBC counts were statistically significant($P<0.05$); at 6 and 12 months, the differences were not statistically significant($P>0.05$).No statistically significant differences were observed in creatinine, urea nitrogen, or eGFR at any time point.

Table 6 Comparison of renal-related indicators between the two groups of children[M(P_{25} , P_{75}), $\bar{x}\pm s$]

Indicator	Time	High-dose group(n=60)	Mini-dose group(n=62)	t/Z	P
24h UTP(g)	Before treatment	3.45±0.35	3.57±0.31	-1.79	0.076
	1-month treatment	2.03±1.05	2.82±0.82	-4.64	<0.001
	3-month treatment	1.26±1.19	2.09±1.37	-3.52	<0.001

URBC(cells/HP)	6-month treatment	0.68±1.01	0.90±1.26	-1.06	0.291
	12-month treatment	0.24±0.63	0.23±0.66	0.04	0.971
	Before treatment	64.50(52.00,91.00)	60.00(53.00,77.25)	-0.40	0.688
	1-month treatment	39.50(26.67,54.47)	52.50(43.20,70.15)	-3.11	0.002
	3-month treatment	18.97(8.00,43.25)	42.65(11.12,62.92)	-2.77	0.006
	6-month treatment	6.00(5.00,19.20)	10.00(10.00,24.41)	-3.72	<0.001
ALB(g/L)	12-month treatment	2.00(2.00,3.00)	2.00(2.00,3.00)	-0.90	0.367
	Before treatment	31.26±6.02	31.70±5.59	-0.40	0.688
	1-month treatment	37.33±5.95	33.48±5.50	3.55	<0.001
	3-month treatment	42.31±5.94	35.92±5.52	5.91	<0.001
	6-month treatment	40.23±5.56	40.02±5.73	0.20	0.839
	12-month treatment	43.06±5.57	41.47±5.23	1.56	0.121
Scr(umol/L)	Before treatment	39.29±2.60	39.80±3.06	-0.99	0.324
	1-month treatment	43.36±2.67	42.88±3.01	0.92	0.360
	3-month treatment	45.06±2.70	44.43±3.15	1.16	0.248
	6-month treatment	46.14±3.34	45.44±3.58	1.09	0.278
	12-month treatment	47.61±4.01	46.67±4.43	1.21	0.228
BUN(mmol/L)	Before treatment	4.21±1.06	4.49±0.96	-1.44	0.153
	1-month treatment	4.52±1.09	4.68±0.96	-0.82	0.414
	3-month treatment	5.17±1.15	5.42±1.04	-1.22	0.225
	6-month treatment	5.51±1.12	5.83±1.12	-1.49	0.139
	12-month treatment	5.67±1.10	5.91±1.09	-1.16	0.249
eGFR(ml/min)	Before treatment	133.55±8.45	131.96±9.39	0.97	0.335
	1-month treatment	127.77±8.12	129.15±8.46	-0.89	0.375
	3-month treatment	124.09±7.67	125.82±8.61	-1.15	0.251
	6-month treatment	123.51±8.66	125.24±8.93	-1.06	0.293
	12-month treatment	122.18±9.62	124.55±10.96	-1.25	0.214

Note: Normally distributed continuous data are expressed as mean±standard deviation($\bar{x}\pm s$), and comparisons between groups were performed using the independent samples t-test. Non-normally distributed continuous data are expressed as median(P₂₅,P₇₅)[M(P₂₅,P₇₅)] and comparisons between groups were performed using the Mann-Whitney U test(rank-sum test for two independent samples). A P-value of <0.05 was considered statistically significant for between-group differences.



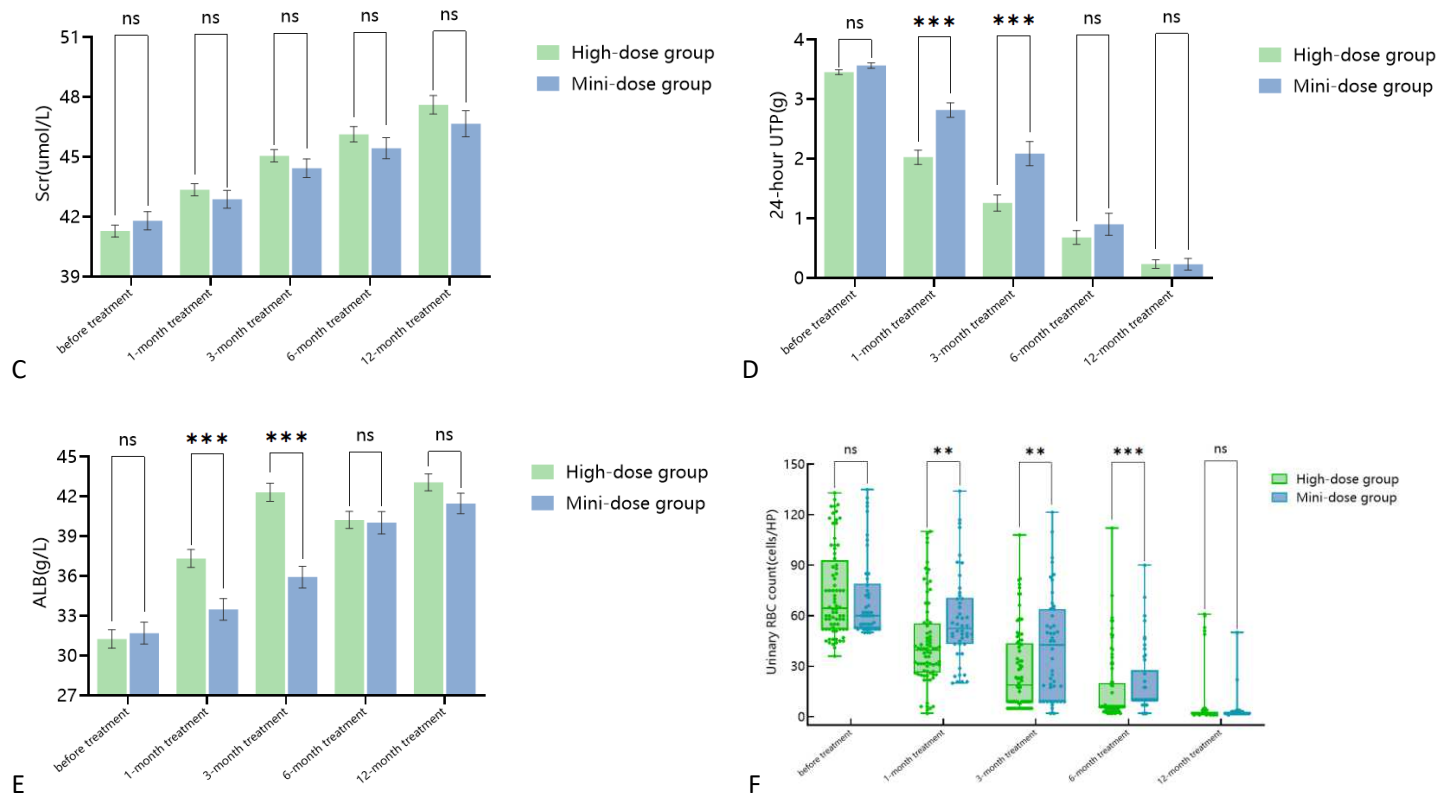


Figure 4 Clinical symptoms and renal function indicators in the two groups before and after treatment

2.2 Immunological indicators In both groups, CD4⁺T-cell and CD4⁺/CD8⁺ ratio showed mild increases after treatment, while CD8⁺ T-cell counts showed a mild decrease. At the same time points, there were no statistically significant differences between groups in CD4⁺, CD8⁺ T-cell counts or CD4⁺/CD8⁺ ratio ($P>0.05$).

Table 7 Comparison of lymphocyte subsets between the two groups at different time points[M(P_{25} , P_{75}), n(%)]

Indicator	Time	High-dose group(n=60)	Mini-dose group(n=62)	Z	P
CD4 ⁺ T(cells/ul)	Before treatment	571.50(396.75,673.75)	578.00(455.50,683.75)	-0.38	0.704
	1-month treatment	577.50(474.75,674.50)	583.00(461.50,689.75)	-0.03	0.977
	3-month treatment	583.00(407.75,684.75)	590.00(467.50,695.75)	-0.47	0.640
	6-month treatment	593.50(417.25,695.75)	601.00(549.50,711.25)	-1.39	0.164
	12-month treatment	659.00(469.25,718.25)	632.50(518.75,740.50)	-0.69	0.492
CD8 ⁺ T(cells/ul)	Before treatment	588.00(476.50,686.25)	622.50(530.25,677.25)	-0.77	0.439
	1-month treatment	586.00(473.50,684.00)	617.50(523.25,673.00)	-0.76	0.447
	3-month treatment	579.00(477.25,681.25)	591.50(524.25,665.25)	-0.23	0.820
	6-month treatment	575.00(469.75,671.25)	590.00(510.75,655.25)	-0.24	0.812
	12-month treatment	571.00(466.00,666.50)	556.50(497.00,618.25)	-1.10	0.271
CD4/CD8	Before treatment	0.96(0.73,1.23)	0.88(0.77,1.11)	-0.85	0.397
	1-month treatment	0.98(0.81,1.23)	0.90(0.77,1.13)	-1.29	0.196
	3-month treatment	0.99(0.71,1.27)	0.93(0.82,1.23)	-0.12	0.901
	6-month treatment	1.03(0.76,1.28)	0.99(0.91,1.22)	-0.51	0.610
	12-month treatment	1.06(0.84,1.38)	1.12(0.93,1.38)	-0.76	0.445

Note: Non-normally distributed continuous data are expressed as median(P_{25} , P_{75}) [M(P_{25} , P_{75})], and comparisons between the two groups were performed using the rank-sum test for two independent samples. A P-value of <0.05 was considered statistically significant for between-group differences.

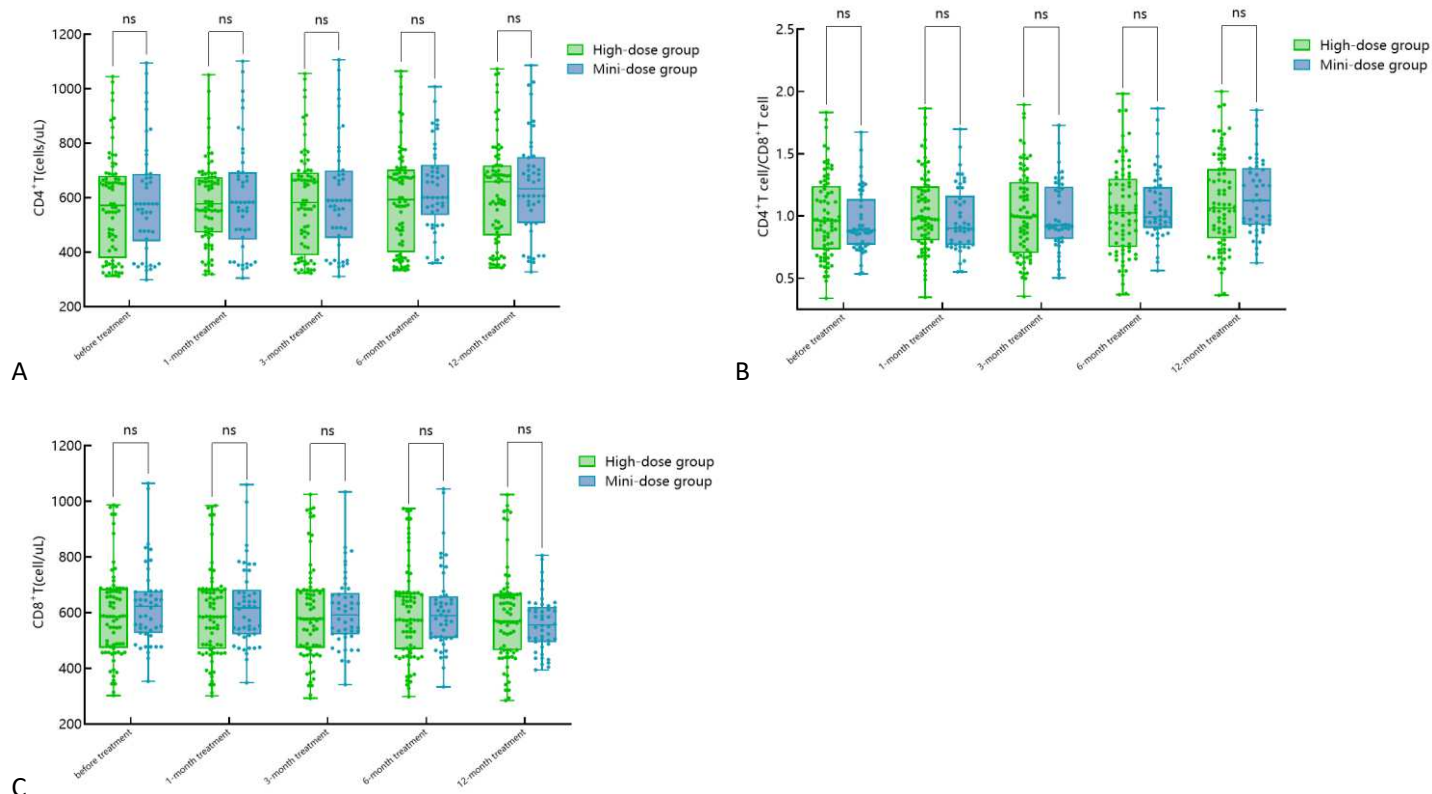


Figure 5 Distribution of lymphocyte subsets in the two groups before and after treatment

3. Prognosis A total of 110 children (90.2%) were followed up in this study, with a loss to follow-up rate of 9.8%. In the high-dose group, 55 cases achieved prognosis grade A, 12 cases achieved grade B, and no cases of grade C or D were observed. In the mini-dose group, 35 cases achieved prognosis grade A, 8 cases achieved grade B, and no cases of grade C or D were observed. There were no statistically significant differences between groups in terms of prognosis grade or recurrence rate.

Table 8 Comparison of prognosis between the two groups[n(%)]

Group	Case	Prognosis grade A	Prognosis grade B	Relapse
High-dose group	67	55(82.1)	12(17.9)	7(10.4)
Mini-dose group	43	36(83.7)	7(16.3)	4(9.3)
χ^2		0.049	0.049	0.038
P		0.825	0.825	0.845

Note: Categorical data are expressed as n (%), and comparisons between the two groups were performed using the chi-square test or Fisher's exact test. A P-value of <0.05 was considered statistically significant for between-group differences.

III. Incidence of Adverse Reactions

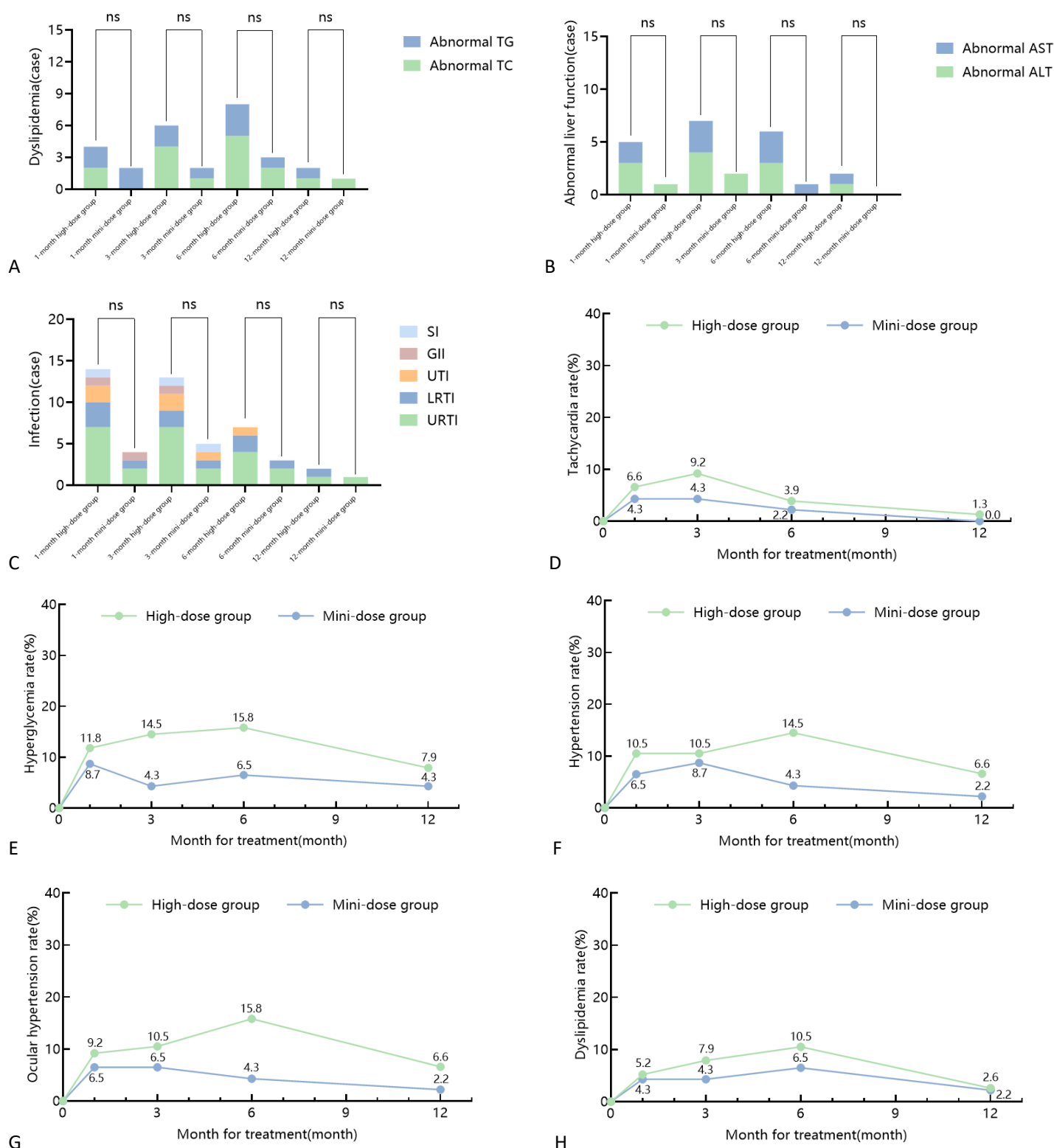
1. Infection

1.1 Infection rate At 1, 3, 6, and 12 months, the differences in infection rates between groups were not statistically significant. At each time point, the infection rate in the high-dose group was higher than that in mini group, with a particularly notable difference during the early treatment period at 1 and 3 months.

1.2 Types of infection Respiratory tract infections were the most common type in both groups. In the high-dose group, the number of cases of upper respiratory tract infections(URTI), lower respiratory tract infections(LRTI), gastrointestinal infection(GII), urinary tract infection(UTI) and skin infections(SI) all showed a decreasing trend over time. At 1 and 3 months, the mini-dose group gradually developed UTI and SI, while

the number of GII decreased. At 6 and 12 months, URTI, LRTI, UTI and SI showed a decreasing trend.

2. Other adverse reactions The most common adverse events in both groups were mild reactions, which improved after symptomatic treatment. No adverse events occurred during the second infusion. No cases of leukopenia, hypogammaglobulinemia, hormone allergy, vasculitic reactions or GI bleeding were observed. Although the differences in the overall incidence of adverse reactions between groups were not statistically significant, the high-dose group had a higher overall incidence of liver injury, blood glucose abnormalities, ocular hypertension, hypertension, dyslipidemia and tachycardia compared with mini group. Among these, ocular hypertension, hypertension and hyperglycemia had a longer duration of occurrence.



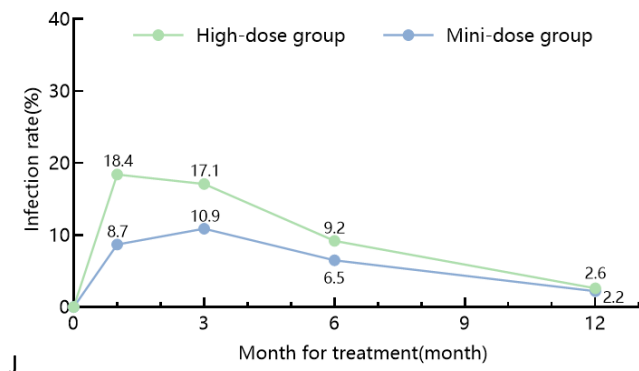
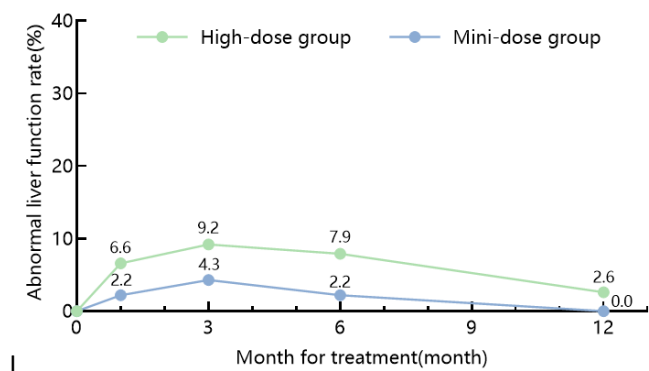


Figure 6 Comparison of adverse reactions between the two groups before and after treatment

Table 9 Adverse reactions in the two groups of children[n(%)]

Type of adverse reactions	1-month treatment				3-month treatment				6-month treatment				12-month treatment			
	High-dose group	Mini-dose group	χ^2	P	High-dose group	Mini-dose group	χ^2	P	High-dose group	Mini-dose group	χ^2	P	High-dose group	Mini-dose group	χ^2	P
Infection	14	4	2.155	0.142	13	5	0.886	0.347	7	3	0.275	0.600	2	1	0.025	0.874
URTI	7	2			7	2			4	2			1	1		
LRTI	3	1			2	1			2	1			1	0		
UTI	2	0			2	1			1	0			0	0		
GII	1	1			1	0			0	0			0	0		
SI	1	0			1	1			0	0			0	0		
Abnormal liver function	5	1	1.189	0.276	7	2	0.992	0.319	6	1	1.734	0.188	2	0	1.231	0.267
ALT	3	1			4	2			3	0			1	0		
AST	2	0			3	0			3	1			1	0		
Dyslipidemia	4	2	0.051	0.821	6	2	0.588	0.443	8	3	0.560	0.454	2	1	0.025	0.874
TC	2	0			4	1			5	2			1	1		
TG	2	2			2	1			3	1			1	0		
Ocular hypertension	7	3	0.270	0.600	8	3	0.088	0.766	12	2	3.693	0.055	5	1	1.189	0.276
Hypertension	8	3	0.560	0.454	8	4	0.108	0.742	11	2	3.086	0.079	5	1	1.189	0.276
Hyperglycemia	9	4	0.298	0.585	11	2	3.086	0.079	12	3	2.282	0.131	6	2	0.588	0.443
Tachycardia	5	2	0.264	0.608	7	2	0.992	0.319	3	1	0.284	0.594	1	0	0.610	0.435

Note: Categorical data are expressed as n(%), and comparisons between the two groups were performed using the chi-square test or Fisher's exact test. A P-value of <0.05 was considered statistically significant for between-group differences.

Strengths and limitations

This is the first study to compare the efficacy and safety of high-dose versus mini-dose MP pulse therapy in children with IgAVN. Patient screening and enrollment were strictly in accordance with guideline indications, and treatment during the study period was rigorously implemented following international standard protocols. No serious adverse events occurred during the study period, and the baseline treatment as well as the dosage and duration of corticosteroid therapy were strictly defined according to standardized international requirements for the treatment of IgAVN. The entire process was carefully monitored, and there were no significant missing values requiring imputation or assumptions. This study employed prognosis grading as the definition of treatment efficacy in children with IgAVN, which provides certain reference value for evaluating renal outcomes in these patients. However, this study has some disadvantages. The single-center retrospective study has several inherent limitations, including non-randomization and selection bias. The mini-group sample included only 46 cases, showing limited sample size. For some adverse events, the p-values between groups were >0.05 , which is likely attributable to insufficient statistical power due to the sample size rather than indicating a true absence of difference, which calls for further validation through multicenter research.

Discussion

There remains some controversy both domestically and internationally regarding the indications for GCs pulse therapy in IgAVN, particularly concerning the dosage and appropriate patient population. The 2026 KDOQI commentary^[36] clearly states that the indications for pulse therapy in children with IgAVN are: ① nephrotic-range proteinuria: urine protein/creatinine ratio >2000 mg/g or 200 mg/mmol; ② rapidly progressive glomerulonephritis(RPGN); ③renal biopsy showing risk of progression: pathological grade (e.g.,ISKDC criteria) $\geq$ grade II. The aim of this study was to compare high-dose and mini-dose MP pulse therapy in children with IgAVN with crescent formation involving $<50\%$ of glomeruli. A total of 122 children with IgAVN and urine protein quantification ≥ 50 mg/kg/24h (nephrotic-range proteinuria^[37]) were enrolled. Compared with previously published data, this study has a larger data volume and a greater number of samples. Laboratory parameters including 24h UTP, URBC count, albumin, renal function indicators, and immunological markers, as well as clinical outcomes including CR, MR, PR, ORR, infection rate and incidence of other adverse reactions, were systematically evaluated to assess the differences in efficacy and safety between high-dose and mini-dose glucocorticoid regimens. Pulse therapy can rapidly induce disease remission to a certain extent, improve remission rates, reduce the long-term risk of relapse, and decrease the total cumulative dose and side effects of long-term corticosteroid use. However, current guidelines and literature have not identified an optimal recommended dose below high-dose pulse therapy. The dosage of 4-6mg/kg/d of GCs has been reported^[26,38-39] in the context of intravenous administration or tapering after high-dose pulse therapy in pediatric critical conditions such as status asthmaticus, severe mycoplasma pneumoniae pneumonia, and some immune-related encephalitis; however, this dosage is largely derived from single-center retrospective case reviews and clinical practice surveys, representing an empirical rescue regimen. Recent studies on corticosteroid therapy^[21] for IgAVN suggest that for children with moderate-to-severe IgAVN(urine protein/creatinine ratio >50 mg/mmol), GCs pulse therapy should be

initiated as early as possible. These studies have shown that the GCs pulse therapy group(15–30 mg/kg/d) had significantly higher remission rates and lower relapse rates compared with the oral corticosteroid group (1.5–2 mg/kg/d), although a number of adverse reaction cases were observed. This is largely consistent with our finding that the high-dose pulse therapy had superior early efficacy compared with the mini-dose group, but was associated with a higher incidence of adverse reactions.

Our results demonstrate that the two regimens achieved comparable efficacy at 6 and 12 months of treatment, while the mini-dose regimen offered better safety and a lower incidence of adverse reactions, providing important reference value and clinical significance for treatment selection. The complete remission and overall response rates of mini-dose MP pulse therapy at 6 and 12 months were not significantly different from those of the high-dose regimen, suggesting that the mini-dose regimen can progressively and effectively control the progression of renal inflammation in children with IgAVN. Mechanistically, GCs exert their effects by binding to intracellular receptors and initiating gene transcription regulation. On one hand, they interfere with the activity of pro-inflammatory transcription factors such as NF- κ B and AP-1 through transrepression, thereby inhibiting the synthesis of key pro-inflammatory cytokines including IL-1, IL-6, and TNF- α ; on the other hand, they promote the expression of anti-inflammatory proteins(such as IL-10 and I κ B α) through transactivation. In IgAVN, GCs can inhibit the proliferation of T and B lymphocytes, reduce the production of pathogenic IgA immune complexes, and attenuate the complement activation and inflammatory cascade triggered by immune complex deposition in the glomeruli, thereby protecting podocytes, repairing the glomerular filtration barrier, and ultimately effectively reducing proteinuria and slowing renal function progression^[40–41]. Thus, renal injury in IgAVN is primarily mediated by complement activation, inflammatory mediators, and cytokine release triggered by immune complex deposition. MP alleviates podocyte immune injury, glomerular mesangial proliferation, and crescent formation by inhibiting the NF- κ B pathway, the JAK-STAT pathway, and reducing the secretion of key inflammatory cytokines such as IL-6, TNF- α , and IL-10. Although the mini-dose regimen has a lower single dose and a slower accumulation to effective concentration during the initial phase, the two-cycle pulse administration followed by sequential oral corticosteroid therapy can gradually and sustainably maintain a potent anti-inflammatory concentration, thereby achieving efficacy comparable to the high-dose regimen. This is similar to the findings of studies^[42] on oral dexamethasone pulse therapy for idiopathic inflammatory myopathy, which showed that dexamethasone pulse therapy had equivalent efficacy to daily prednisone but with a better safety profile. From a clinical practice perspective, the mini-dose regimen, while ensuring anti-inflammatory efficacy, can reduce GCs exposure and the cumulative side effects associated with high-dose therapy. It is particularly suitable for younger children, those with high body weight, those with poor baseline physical condition, those at high risk of corticosteroid-related adverse reactions(such as obesity, unstable blood glucose, family history of hypertension), or those with concurrent severe infections, thereby providing more options for individualized clinical treatment.

The most significant finding of this study is that the mini-dose group had a more favorable infection profile, with lower infection rates and lower incidences of adverse reactions. The infection rate in the high-dose group within 12 months was significantly higher than that in the mini-dose group, which is related to the potent immunosuppressive effect of high-dose corticosteroids—corticosteroids can reduce

lymphocyte counts, inhibit neutrophil migration and cytotoxic function, and suppress macrophage function, thereby reducing the body's anti-infection capacity and increasing the risk of viral or bacterial infections. In addition, the high-dose group had more cases of various types of infections than the mini-dose group, suggesting that the infection-related negative impact of the high-dose group was worse than that of the mini-dose group. This may be related to the early cumulative response of corticosteroids, the instantaneous peak concentration, and sustained cellular immune stimulation. Over time, the resolving capacity of the two-course high-dose corticosteroid pulse therapy was far lower than the cumulative effect of subsequent sequential oral corticosteroids, thereby amplifying the risk of immune dysregulation and metabolic imbalance. In contrast, because the mini-dose regimen starts with a lower initial corticosteroid dose, drug turnover occurs before the cycle interval, conferring advantages of faster metabolism and earlier renewal, which significantly reduces the likelihood of infection-related adverse effects. Furthermore, the incidences of abnormal liver function, glucose abnormalities, dyslipidemia, ocular hypertension, hypertension, and tachycardia in the mini-dose group were significantly lower than those in the high-dose group. This is because the high-dose regimen imposes an excessive peak concentration burden with sustained degradation, promoting hepatic glycogen breakdown, enhanced gluconeogenesis, lipid redistribution, and sodium and water retention, which predispose to metabolic disturbances in nutrients, water, and electrolytes. In contrast, the mini-dose regimen reduces the risk of the aforementioned adverse reactions through gradual dose tapering. Given that the two regimens are comparable in controlling renal inflammatory progression, the reduction in corticosteroid-related adverse reactions not only improves patient compliance but also reduces the probability of long-term corticosteroid-related complications such as diabetes, hypertension, dyslipidemia, osteoporosis, and gastrointestinal dysfunction, which is of great significance for improving the long-term quality of life of children with IgAVN. In conclusion, mini-dose MP pulse therapy is equally effective as the high-dose regimen in children with IgAVN with crescent formation involving <50% of glomeruli, and is associated with lower infection rates and fewer adverse reactions, offering a safer and more effective alternative treatment strategy for these selected patients population.

Ethics statement

The data and materials involved in this article have been reviewed and approved by the Ethics Committee of the Affiliated Hospital of Xuzhou Medical University(Ethics Committee Approval Number: XYFY2026-KL365-01).

Informed Consent

The retrospective study obtained ethical approval, and the requirement for written informed consent was waived by ethics committee due to its retrospective nature.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author contributions

Huang Lan and Yue Yang were responsible for drafting and refining the manuscript. Zhu Yuanhui and Hao Houhua conducted information searches and collected critical data. Guan Fengjun contributed by reading and revising the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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