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Original Research Article

Outcome of low dose daily versus standard alternate day prednisolone for frequent relapse nephrotic syndrome in children

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ABSTRACT

Background: Nephrotic syndrome is a common chronic glomerular disorder in children, with frequent relapses causing significant clinical and psychosocial burden. Prednisolone remains the cornerstone of therapy, typically administered on an alternate-day schedule for maintenance. However, low daily-dose regimens may improve relapse control with fewer adverse effects, particularly in resource-limited settings.
Methods: This quasi-experimental study included 72 children aged 2-12 years with FRNS treated at the National Institute of Kidney Diseases and Urology, Dhaka, between August 2022 and August 2024. Participants received either daily low-dose prednisolone (0.2 mg/kg; Group A, n=31) or alternate-day prednisolone (0.5 mg/kg; Group B, n=32) for six months. Clinical features, anthropometric measurements, laboratory findings, relapse frequency, and steroid-related adverse effects were assessed at baseline, 3 months, and 6 months. Data were analyzed using independent T-tests and chi-square tests, with $p<0.05$ considered significant.
Results: Baseline characteristics were comparable. At 6 months, oedema, ascites, and significant proteinuria were more frequent in Group B (70% vs. 41.4%, p=0.027). Group A had a lower cumulative prednisolone dose (60.57±24.79 mg/kg vs. 76.01±14.21 mg/kg, p=0.005), fewer Cushingoid features (3.4% vs. 20%, p=0.049), better BMI preservation, lower relapse rates (41.4% vs. 70%, p=0.027), and higher remission rates (58.6% vs. 30%, p=0.027).
Conclusions: Daily low-dose prednisolone appears more effective and safer than the standard alternate-day regimen in maintaining remission in children with FRNS.

Keywords: Frequent-relapse nephrotic syndrome, Paediatric nephrology

INTRODUCTION

Nephrotic syndrome is one of the most common chronic glomerular disorders in the childhood, characterized by the heavy proteinuria, hypoalbuminemia, edema, and the hyperlipidemia. While most of the children initially respond well to the corticosteroid therapy, a significant proportion experience the repeated relapses, often leading to the classification of frequent relapse nephrotic syndrome (FRNS). These repeated relapses place a considerable and clinical psychological burden on affected children and their families, underscoring the need for optimized therapeutic strategies that balance efficacy with safety.[1-4] Prednisolone remains the cornerstone of therapy for childhood nephrotic syndrome. The traditional regimen for maintaining remission in

FRNS has been alternate-day prednisolone, which aims to reduce relapse frequency while minimizing steroid-related adverse effects. However, concerns about inadequate immunomodulation during off-steroid days and the persistence of relapses in some children have led to the exploration of alternative dosing strategies.[5] One such approach is a low daily dose regimen, which provides steady immunosuppression with the goal of improving relapse control.

Recent studies suggest that low daily prednisolone may offer superior relapse prevention compared to alternate-day dosing, particularly in children with highly relapse-prone disease. However, daily steroid exposure raises concerns about cumulative toxicity, including growth retardation, obesity, hypertension, cataracts, and behavioral changes.[6-8] Thus, striking the right balance between therapeutic benefit and potential harm remains a major challenge in long-term management. Evaluating the comparative outcomes of these two regimens is therefore essential to guide evidence-based clinical decision-making.

In many low- and middle-income countries, including Bangladesh, treatment practices for FRNS vary widely due to differences in clinician preference, resource availability, and patient follow-up patterns. Local data comparing low daily dose prednisolone with the standard alternate-day regimen are limited, yet such evidence is crucial for informing practice guidelines tailored to resource-constrained settings.[9-11] Understanding which regimen provides better relapse control with fewer adverse effects can directly improve quality of life and long-term prognosis in affected children.

METHODS

Study design

This investigation followed a quasi-experimental study design to evaluate treatment outcomes among children with frequent relapse nephrotic syndrome.

Study place

The study was conducted in the Department of Pediatric Nephrology at the National Institute of Kidney Diseases and Urology (NIKDU), located in Sher-E-Bangla Nagar, Dhaka.

Study period

Data collection and follow-up were carried out over a two-year period, from August 2022 to August 2024.

Study population

The study population comprised both inpatient and outpatient children diagnosed with frequent relapse nephrotic syndrome under the Pediatric Nephrology Department at NIKDU.

Sampling method

A non-probability sampling technique was employed to select eligible participants.

Sample size

Sample size estimation was based on previously reported sustained remission rates in comparable therapy groups, applying standard statistical parameters for confidence interval and power. The sample size consisted of thirty-six participants in each group.

Selection criteria

Children aged two to twelve years presenting with frequent relapse nephrotic syndrome at relapse were considered eligible. Exclusion criteria included secondary nephrotic syndrome, impaired renal function, prior treatment with steroid-sparing agents, steroid-resistant or steroid-dependent nephrotic syndrome, and evidence of steroid toxicity.

Study variables

Demographic variables included age, gender, and baseline clinical characteristics. Clinical variables encompassed weight, height, temperature, presence of oedema or ascites, BMI, respiratory findings, blood pressure, cushingoid facies, BSUA results, ophthalmologic findings, and cumulative prednisolone dose. Laboratory parameters included complete blood count, random blood sugar, serum creatinine, urine routine and culture, serum albumin, serum cholesterol, urinary protein–creatinine ratio, and chest radiographs. Outcome variables assessed relapse frequency, remission rates, and steroid-related adverse effects.

Data collection procedure

A total of seventy-two children who fulfilled the inclusion criteria were enrolled after obtaining ethical approval from the institutional review board. Data were recorded using a structured questionnaire, and written informed consent was obtained from parents or guardians. Participants retained the right to withdraw at any stage without affecting their treatment.

A detailed history and thorough physical examination were performed at enrollment. Standard laboratory investigations including complete blood count (optical flow cytometric method), serum creatinine (enzymatic method), serum albumin and cholesterol (autoanalyzer), urine routine microscopy and culture (Vitek system), urinary protein–creatinine ratio, and chest X-ray—were completed. Screening for infections was conducted and managed according to clinical guidelines.

All enrolled children received prednisolone at 2 mg/kg/day until urine became protein-free for three consecutive days. One participant was lost to follow-up during this phase, and four children who failed to achieve remission were categorized as steroid-resistant and were excluded. After remission, prednisolone was continued following a tapering regimen: 1.5 mg/kg every alternate day for four weeks, followed by 1 mg/kg every alternate day for two weeks, and then 0.75 mg/kg every alternate day for another two weeks. After completion of this tapering schedule, patients were assigned to one of two maintenance therapy groups: a daily low-dose regimen of 0.2 mg/kg (Group A) or a standard alternate-day regimen of 0.5 mg/kg (Group B), continued for six months as described by Yadav et al (2019). During relapse episodes, children in both groups received prednisolone 2 mg/kg/day until remission for three consecutive days, followed by 1.5 mg/kg every alternate day for four weeks. After completing relapse management, patients resumed their respective maintenance therapies.

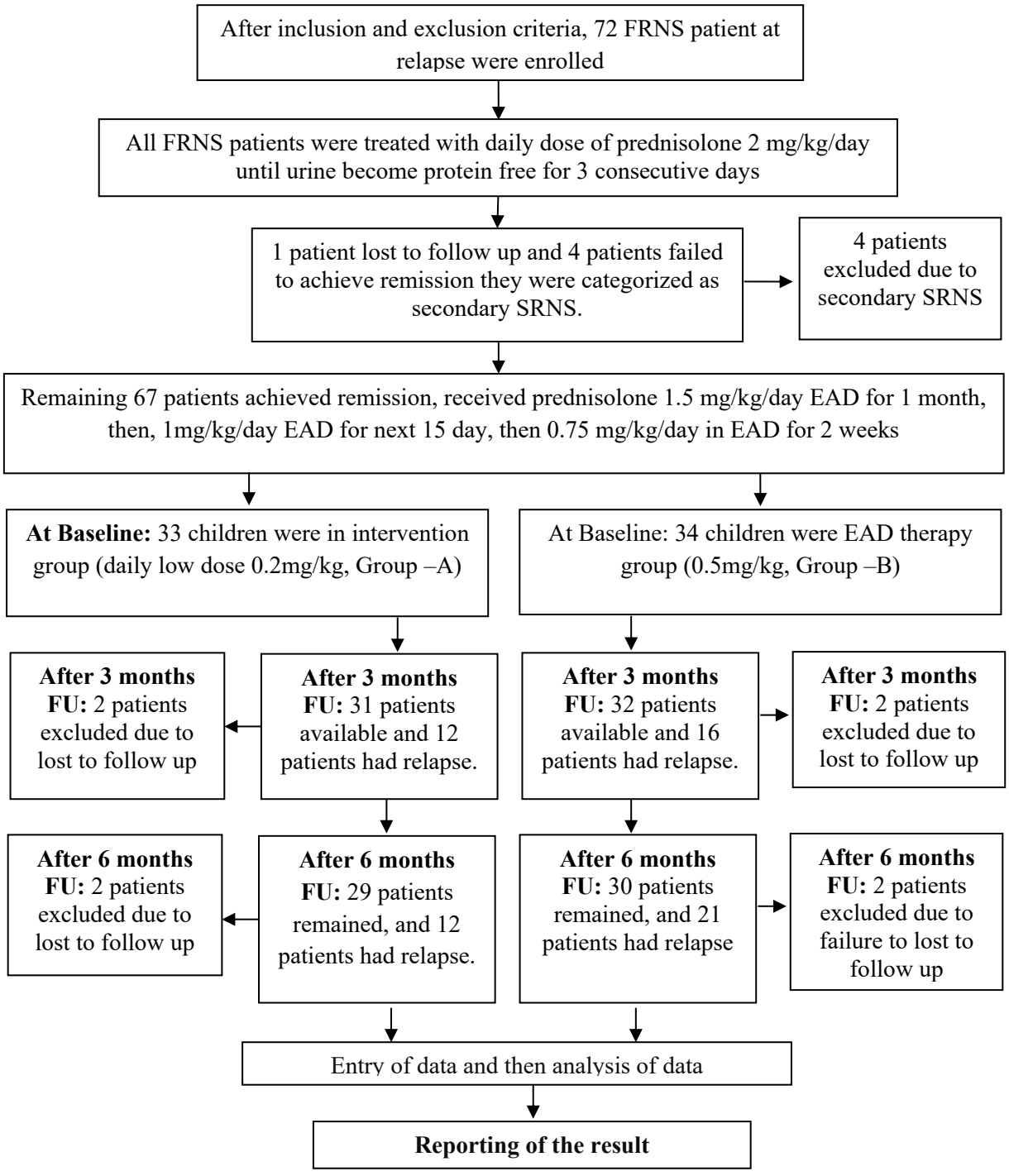

Figure 1: Study flow diagram of patient enrollment and follow-up.

Follow-up visits were scheduled at three-month intervals or earlier during relapse. A few participants from both groups were lost to follow-up at the three-month and six-month evaluations. Families were instructed to perform BSUA testing daily during relapse and two to three times weekly during remission.

Monitoring dairies documenting urine test results and medication adherence were reviewed at each visit. During follow-up assessments, general appearance, vital signs, anthropometric measurements, and signs of oedema or ascites were examined. Laboratory investigations were repeated at three and six months or earlier during relapse episodes. In cases of missed appointments, families were contacted and an alternative visit was arranged within ten days. Additional guidance was provided via telephone or through local physicians when required.

Data collection was performed by the principal investigator using structured case record forms. Statistical analysis was carried out using SPSS version 26.

Data collection tools

Data were collected using patient checklists, informed consent forms in Bangla and English, physical examination instruments, laboratory reports, and a structured questionnaire.

Data processing and analysis

All collected data were checked for accuracy and processed using SPSS version 26. Qualitative variables were summarized using frequencies and percentages, while quantitative data were expressed as mean and standard deviation. Independent sample T-tests were applied to compare continuous variables, and chi-square tests were used for categorical data. A P-value of less than 0.05 was considered statistically significant. Results were presented in tables, figures, and graphs as required.

Ethical considerations

The study protocol was reviewed and approved by the ethical and research review committees of NIKDU. Study aims and procedures were explained to caregivers in the local language using printed materials, and written informed consent was obtained. Participants were assured of confidentiality, informed that there was no financial incentive, and reminded that withdrawal from the study would not affect their medical care. It was also emphasized that the study did not involve any invasive procedures.

RESULTS

Children aged 2-12 years with frequent relapse nephrotic syndrome enrolled based on selection criteria. Mean age of every alternate day group was 5.30±2.00 and mean age of the daily day dose was 5.54±2.20. Also, age of disease onset was 3.08±1.24 years in group A and 3.38±1.42 years in group B Table 1. The study included 63 children with frequently relapsing nephrotic syndrome, divided into Group A (daily low-dose prednisolone 0.2 mg/kg, n=31) and Group B (alternate-day prednisolone 0.5 mg/kg, n=32).

Table 1: Age distribution of the participants (n=72).

Age (years)	Group A (mean ± SD)	Group B (mean ± SD)	P value**
Age (2-12)	5.54 ±2.20	5.30 ±2.00	>0.910
Age of onset (2-8)	3.08±1.24	3.38±1.42	0.342

**Independent t test was done

Table 2: Clinical variable in 3 months follow up of the participants.

Variable	Group A, daily low dose 0.2mg/kg, n=31 Mean (SD)/N (%)	Group B, alternate day 0.50mg/kg, n=32 Mean (SD)/N (%)	P value
Weight (kg)	20.01 (4.85)	21.15 (6.92)	0.452**
Height (cm)	113.02 (13.08)	111.38 (11.64)	0.601**
BMI (kg/m^2)	15.53 (1.51)	16.13(1.71)	0.146**
Systolic BP (MMHG)	98.39 (7.45)	94.06 (8.27)	0.033**
Diastolic BP (MMHG)	56.77 (5.71)	56.41 (4.96)	0.785**
Normal temperature, N (%)	31 (100.00)	32 (100.00)	-
Oedema, N (%)	12 (38.7)	16 (50)	0.367*
Ascites, N (%)	12 (38.7)	16 (50)	0.367*
BSUA, N (%)			
+++	10 (32.2)	11 (34.4)	0.803*
++++	2 (6.5)	5 (15.6)	

*Chi-square test was done, and **Independent t test was done

Table 3: Laboratory parameters of 3 months follow up of the participants.

Parameters	Group A, daily low dose 0.2 mg/kg, n=31, N (%)	Group B, alternate day 0.50 mg/kg, n=32, N (%)	P value
Urine albumin (+++)	12 (38.7)	16 (50)	0.367*
Urine spot protein creatinine ratio (>2)	12 (38.7)	16 (50)	0.367*
Urine C/S			
No growth	31 (100.00)	32 (100.00)	-
Urine RE			
Normal	31 (100.00)	32 (100.00)	-
Mean serum creatinine (mg/dl)	0.46 (0.08)	0.48 (0.11)	0.560**
Mean serum albumin (gm/dl)	2.81 (0.86)	2.59 (0.96)	0.343**
Mean serum cholesterol (mg/dl)	258.83 (54.74)	280.25 (65.6)	0.165**

*Chi-square test was done; **Independent t test was done

Table 4: Clinical variable in 6 months follow up of the participants.

Variable	Group A daily low dose 0.2 mg/kg, n=31, N (%)	Group B, alternate day 0.50 mg/kg, n=32, N (%)	P value
Weight (kg)	20.46 (5.25)	20.1 (4.95)	0.835**
Height (cm)	113.26 (13.19)	111.76 (11.57)	0.640**
BMI (kg/m2)	15.8 (1.57)	15.95 (1.58)	0.711**
Systolic BP (MMHG)	100.83 (8.82)	98.62 (8.01)	0.318**
Diastolic BP (MMHG)	58.62 (6.39)	58.17 (7.01)	0.796**
Normal temperature, N (%)	29 (100.00)	30 (100.00)	-
Oedema, N (%)	12 (41.4)	21 (70)	0.027*
Ascites, N (%)	12 (41.4)	21 (70)	0.027*
BSUA, N (%)			
+++	3 (10.3)	7 (23.3)	0.280*
++++	9 (31.1)	14 (46.7)	

*Chi-square test was done; **Independent t test was done

Table 5: Laboratory parameters of 6 months follow up of the participants.

Parameters	Group A, daily low dose 0.2 mg/kg, n=31, N (%)	Group B, alternate day 0.50 mg/kg, n=32, N (%)	P value
Urine albumin +++	12 (41.4)	21 (70)	0.027*
Urine spot protein creatinine ratio (>2)	12 (41.4)	21 (70)	0.027*
Urine C/S			
No growth	29 (100.00)	30 (100.00)	-
Urine RE			
Normal	29 (100.00)	30 (100.00)	-
Mean serum creatinine (mg/dl)	0.49 (0.09)	0.48 (0.09)	0.539**
Mean serum albumin (gm/dl)	2.36 (0.79)	2.04 (0.62)	0.088**
Mean serum cholesterol (mg/dl)	259.65 (61.6)	271.9 (73.89)	0.493**

*Chi-square test was done; **Independent t test was done

Table 6: Side effects in 3 months follow up of the participants.

Variable	Group A, daily low dose 0.2 mg/kg, n=31, N (%)	Group B, alternate day 0.50 mg/kg, n=32, N (%)	P value
HTN N (%)	0	0	-
Hyperglycemia	0	0	-
Cataract/glaucoma	0	0	-
Cushingoid facies N (%)	1 (3.2)	0	0.306*
BMI category N (%)			
Healthy weight	31 (100%)	32 (100%)	-

Baseline anthropometric parameters, including weight (20.01± 4.85 vs. 21.15± 6.92 kg, p=0.452), height (113.02 ± 13.08 vs. 111.38±11.64 cm, p=0.601), and BMI (15.53±1.51 vs. 16.13±1.71 kg/m², p=0.146) were comparable between groups. Systolic blood pressure was slightly higher in Group A (98.39±7.45 vs. 94.06±8.27 mmHg, p=0.033), while diastolic blood pressure did not differ significantly (56.77±5.71 vs. 56.41±4.96 mmHg, p=0.785). All participants had normal body temperature. Oedema and ascites were present in 38.7% of Group A and 50% of Group B (p=0.367 for both), and urinalysis showed similar distributions of +++ and ++++ proteinuria (32.2% vs. 34.4% and 6.5% vs. 15.6%, p=0.803), indicating comparable clinical and laboratory profiles across both steroid regimens Table 2. Laboratory evaluation showed that urine protein parameters were comparable between groups, with 38.7% of Group A and 50% of Group B exhibiting +++ albuminuria and urine spot protein-creatinine ratio >2 (p=0.367 for both).

Urine cultures revealed no growth in all participants, and routine urine examination was normal in 100% of cases in both groups. Mean serum creatinine levels were similar (0.46±0.08 vs. 0.48±0.11 mg/dl, p=0.560), as were mean serum albumin (2.81±0.86 vs. 2.59±0.96 g/dl, p=0.343) and mean serum cholesterol (258.83±54.74 vs. 280.25±65.6 mg/dl, p=0.165), indicating no significant differences in renal function or biochemical parameters between the daily low-dose and alternate-day prednisolone groups Table 3.

At follow-up, both groups had comparable anthropometric and vital parameters, with mean weight (20.46±5.25 vs. 20.18±4.95 kg, p=0.835), height (113.26 ±13.19 vs. 111.76±11.57 cm, p=0.640), BMI (15.8±1.57 vs. 15.95±1.58 kg/m², p=0.711), systolic BP (100.83± 8.82 vs. 98.62±8.01 mmHg, p=0.318), and diastolic BP (58.62±6.39 vs. 58.17±7.01 mmHg, p=0.796) showing no significant differences. All participants maintained normal body temperature. However, oedema and ascites were significantly more frequent in Group B (70% vs. 41.4%, p=0.027 for both). Urinalysis revealed +++ and ++++ proteinuria in 10.3% and 31.1% of Group A versus 23.3% and 46.7% of Group B, respectively, without reaching statistical significance (p=0.280), indicating that both daily low-dose and alternate-day prednisolone regimens generally maintained clinical stability, though fluid retention appeared more pronounced in the alternate-day group Table 4. Laboratory assessment showed that significant proteinuria was more frequent in Group B, with 70% exhibiting +++ urine albumin and urine spot protein-creatinine ratio >2 compared to 41.4% in Group A (p=0.027 for both). Urine cultures showed no growth, and routine urine examination was normal in all participants.

Mean serum creatinine levels were similar between groups (0.49±0.09 vs. 0.48±0.09 mg/dl, p=0.539), as were mean serum albumin (2.36±0.79 vs. 2.04±0.62 g/dl, p=0.088) and mean serum cholesterol (259.65±61.6 vs. 271.9±73.89 mg/dl, p=0.493), indicating comparable renal function and biochemical profiles despite the higher proteinuria observed in the alternate-day prednisolone group. Table 5 Assessment of treatment-related adverse effects revealed no cases of hypertension, hyperglycemia, or cataract/glaucoma in either group. Cushingoid facies was observed in only one child in Group A (3.2%) and none in Group B (p=0.306). All participants maintained a healthy weight, with 100% in both groups falling within the normal BMI category, indicating that both daily low-dose and alternate-day prednisolone regimens were generally well tolerated without significant metabolic or ocular complications Table 6. During follow-up, hypertension was observed in 6.9% of Group A and 10% of Group B (p=0.669), while no participants in either group developed hyperglycemia or cataract/glaucoma.

Cushingoid facies was significantly more frequent in the alternate-day group (20% vs. 3.4%, p=0.049). Regarding BMI, the majority of Group A remained in the healthy weight category (96.6%), compared to 23.3% in Group B, with a small proportion classified as overweight in both groups (3.4% vs. 13.3%, p=0.173).

Table 7: Side effects in 6 months follow up of the participants.

Variable	Group A, daily low dose 0.2 mg/kg, n=31 N (%)	Group B, alternate day 0.50 mg/kg, n=32 N (%)	P-value
HTN, n (%)	2 (6.9)	3 (10)	0.669*
Hyperglycemia n (%)	0	0	-
Cataract/glaucoma n (%)	0	0	-
Cushingoid facies n (%)	1 (3.4)	6 (20)	0.049*
BMI category n (%)			
Healthy weight	28 (96.6)	7 (23.3)	0.173*
Overweight	1 (3.4)	4 (13.3)	

*Chi-square test was done

Table 8: Cumulative prednisolone dose after 6 months of follow-up.

	Group A, daily low dose 0.2 mg/kg, n=31 N (%)	Group B, alternate day 0.50 mg/kg, n=32 N (%)	Mean difference	P-value*
Cumulative dose of prednisolone (mg/kg)	60.57±24.79	76.01±14.21	15.43	0.005

*Independent t test was done

Table 9: Findings comparing low-dose daily with standard alternate-day prednisolone.

	Group A, daily low dose 0.2mg/kg, n=31 N (%)	Group B, alternate day 0.50mg/kg, n=32 N (%)	P-value*
Relapse at 3 months	12 (38.7)	16 (50)	0.367
Relapse at 6 months	12 (41.4)	21 (70.0)	0.027

*Chi-square test was done

These findings suggest that daily low-dose prednisolone was generally better tolerated with fewer steroid-related adverse effects compared to the alternate-day regimen. Table 7 The cumulative prednisolone dose over the study period was significantly lower in the daily low-dose group (60.57±24.79 mg/kg) compared to the alternate-day group (76.01±14.21 mg/kg), with a mean difference of 15.43 mg/kg (p=0.005), indicating that the daily low-dose regimen achieved disease management with a reduced total steroid exposure Table 8. Relapse rates were comparable between groups at 3 months (38.7% in

Group A vs. 50% in Group B, p=0.367); however, by 6 months, relapses were significantly higher in the alternate-day group (70% vs. 41.4%, p=0.027), suggesting that daily low-dose prednisolone was more effective in maintaining remission over time Table 9.

DISCUSSION

This study evaluated the efficacy and safety of daily low-dose prednisolone (0.2 mg/kg) versus standard alternate-day prednisolone (0.5 mg/kg) in children aged 2–12 years with FRNS. The mean age of participants in the daily low-dose and alternate-day groups was similar (5.54± 2.20 vs. 5.30±2.00 years), as was the age of disease onset (3.08±1.24 vs. 3.38±1.42 years), reflecting comparable baseline characteristics. These findings are consistent with which also reported no significant differences in the age distribution or age of onset between the different steroid regimens in FRNS.[9-11]

Clinical and anthropometric parameters were largely comparable between the two groups at baseline and during follow-up. Weight, height, BMI, and vital signs showed no significant differences, although systolic blood pressure was slightly higher in the daily low-dose group at 3 months (p=0.033). Oedema and ascites were more pronounced in the alternate-day group at 6 months (70% vs. 41.4%, p=0.027), suggesting slightly better fluid balance in children receiving daily low-dose therapy.

Similar findings were reported who noted comparable growth parameters but reduced edema frequency in low-dose daily regimens compared to alternate-day therapy.[12] Laboratory parameters, including urine protein levels, serum creatinine, albumin, and cholesterol, were largely comparable between groups, although significant proteinuria was more frequent in the alternate-day group at 6 months (70% vs. 41.4%, p=0.027). These results align with the observations where daily low-dose prednisolone was associated with lower proteinuria and better biochemical stability over time.[13] Urine cultures and routine urine examinations remained normal in all participants, reflecting preserved renal function in both regimens. The cumulative prednisolone dose was significantly lower in the daily low-dose group (60.57±24.79 mg/kg vs. 76.01±14.21 mg/kg, p=0.005), demonstrating that effective disease management can be achieved with reduced total steroid exposure. Reduced steroid burden is clinically relevant because it minimizes the risk of adverse effects, a finding supported by studies which reported lower cumulative steroid doses with daily low-dose regimens while maintaining remission.[14]

Adverse effects were generally mild in both groups. Hypertension and hyperglycemia were rare, while Cushingoid facies was significantly more frequent in the alternate-day group at 6 months (20% vs. 3.4%, p=0.049). BMI remained predominantly in the healthy range in the daily low-dose group, whereas some children in the alternate-day group developed overweight status. These findings highlight the safety advantage of daily low-dose therapy, corroborating previous studies which demonstrated fewer steroid-related complications with lower daily dosing.[15]Relapse rates and remission outcomes further supported the efficacy of daily low-dose prednisolone. Although 3-month relapse rates were similar between groups, the 6-month relapse rate was significantly lower in the daily low-dose group (41.4% vs. 70%, p=0.027), and remission was achieved in a higher proportion of children (58.6% vs. 30%, p=0.027). This suggests that daily low-dose therapy may provide

superior long-term disease control, consistent with the findings who reported improved remission maintenance with daily low-dose regimens in FRNS.[16]

CONCLUSION

Based on our results, children with frequently relapsing nephrotic syndrome treated with daily low-dose prednisolone (0.2 mg/kg) demonstrated comparable clinical and laboratory stability to those receiving standard alternate-day therapy (0.5 mg/kg), while achieving significantly lower cumulative steroid exposure, fewer steroid-related adverse effects, reduced relapse rates, and higher remission rates at 6 months. These findings suggest that daily low-dose prednisolone is an effective and safer alternative for maintaining remission in children with frequently relapsing nephrotic syndrome.

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