

## Original Research Article

# Efficacy and safety of deflazacort in children with an initial episode of idiopathic nephrotic syndrome - a randomized controlled trial

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## ABSTRACT

**Background:** Idiopathic nephrotic syndrome (INS) is the most common glomerular disease in children. Prednisolone has been the standard first-line therapy, but deflazacort, a synthetic corticosteroid, has shown promise with potentially fewer side effects. This study aimed to compare the efficacy and safety of deflazacort versus prednisolone in children with an initial episode of INS.

**Methods:** This randomized controlled trial was conducted in the Department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology (NIKDU), Dhaka, Bangladesh, from June 2019 to January 2021. In this study, we included 83 children, aged 2 to 12 years, who had Idiopathic nephrotic syndrome and visited the outdoor department and were admitted to the pediatric nephrology department of NIKDU. Patients were divided into two treatment groups – group A patients were prescribed prednisolone, and group B patients were prescribed deflazacort.

**Results:** The mean age was significantly higher in the deflazacort group ( $4.97 \pm 2.11$  years) compared to the prednisolone group ( $3.87 \pm 1.23$  years), with a statistically significant p value of 0.007. The mean time to induce remission was significantly shorter in the deflazacort group ( $7.87 \pm 3.33$  days) compared to the prednisolone group ( $9.82 \pm 3.43$  days;  $p=0.02$ ). Although relapse rates were higher in the prednisolone group at 3 and 6 months, the differences were not statistically significant. Complications like moon face and buffalo hump occurred more frequently in the prednisolone group, but without statistical significance. No significant differences were observed in growth parameters, blood pressure, cholesterol, or random blood sugar (RBS) levels between the two groups during follow-up.

**Conclusions:** This study showed that deflazacort induced remission in a shorter time compared to prednisolone in children with an initial episode of INS. While both treatments were similarly effective in achieving remission, the deflazacort group experienced fewer relapses and a lower incidence of side effects during the follow-up period.

**Keywords:** Idiopathic nephrotic syndrome, Deflazacort, Prednisolone, Children

## INTRODUCTION

Nephrotic syndrome is a common pediatric kidney disorder characterized by heavy proteinuria, hypoalbuminemia (serum albumin  $<2.5$  g/dl), hyper-lipidemia

(serum cholesterol  $>200$  mg/dl), and edema.<sup>1</sup> In developed countries, the incidence ranges from 2 to 7 per 100,000 children, with a prevalence of around 15 per 100,000 in those under 16 years of age.<sup>2</sup> However, the incidence is significantly higher in the Indian subcontinent, estimated

at 90 to 100 per million population, compared to 20 to 40 per million in Western countries.<sup>3</sup> Nephrotic syndrome is particularly common among young children in South Asia.<sup>4</sup>

Approximately 95% of nephrotic syndrome cases in children are primary, meaning they occur without an identifiable cause. The remaining cases result from renal involvement in systemic diseases.<sup>5</sup> Effective treatments for this condition only emerged in the mid-20th century with the introduction of corticosteroids, antibiotics, diuretics, and other immunomodulatory therapies. Corticosteroids were first isolated in 1936, and by the early 1950s, intramuscular cortisone and adrenocorticotrophic hormone (ACTH) were being used to treat nephrotic syndrome in children.<sup>6,7</sup> These therapies significantly reduced mortality, bringing it down to around 3%.<sup>8</sup>

The initial management of nephrotic syndrome has traditionally involved corticosteroid therapy. The International Study for Kidney Diseases in Children (ISKDC) originally recommended a regimen of 4 weeks of daily prednisolone followed by 4 weeks on alternate days.<sup>9</sup> While this regimen was widely adopted for decades, later studies suggested that extending the duration of steroid therapy to 12 weeks or more significantly reduced relapse rates. However, this comes at the cost of increased adverse effects.<sup>10</sup>

Prednisolone, the most commonly used steroid in nephrotic syndrome, has predominant glucocorticoid and minimal mineralocorticoid activity, making it effective in treating immune-mediated diseases such as nephrotic syndrome and systemic lupus erythematosus.<sup>11</sup> In idiopathic nephrotic syndrome (INS), its efficacy stems from both immunosuppressive and anti-inflammatory actions. However, prolonged use in children can lead to significant side effects, including obesity, growth retardation, hypertension, impaired glucose tolerance, hyperlipidemia, osteoporosis, cushingoid features, and adrenal suppression.<sup>12</sup> These concerns have led to a search for alternative therapies with fewer long-term side effects.<sup>13</sup>

Deflazacort, a synthetic glucocorticoid introduced in 1969, is structurally similar to cortisol but features a D-ring substitution. It has been used in conditions such as Duchenne muscular dystrophy (DMD), juvenile idiopathic arthritis (JIA), renal transplant recipients, hematological disorders like non-Hodgkin lymphoma, idiopathic thrombocytopenic purpura, and refractory epilepsy.<sup>13</sup>

In the context of nephrotic syndrome, deflazacort has shown promise as an alternative to prednisolone. Studies by Penazzola et al and Lee et al found that deflazacort was associated with milder side effects and, in some cases, superior efficacy in maintaining remission among patients with steroid-dependent nephrotic syndrome.<sup>14,15</sup>

Comparative studies, including those by Broyer et al, noted that deflazacort was linked to less weight gain and milder cushingoid features.<sup>16</sup> It also resulted in a lesser decline in growth velocity and better final height outcomes after 1–2 years of use. According to Kurt et al, deflazacort's pharmacokinetic advantages, such as faster intestinal absorption, shorter plasma half-life, and longer receptor binding in renal and thymic tissues, contribute to its lower toxicity profile.<sup>17</sup> Elli et al further reported that deflazacort causes fewer mineralocorticoid-related side effects and more favorable calcium and phosphate metabolism compared to prednisolone.<sup>18</sup>

Clinical outcomes with deflazacort are encouraging. Remission rates are comparable between deflazacort and prednisolone, though remission may be achieved more quickly with deflazacort. Furthermore, longitudinal studies have shown a significant difference in height gain, favoring deflazacort over prednisolone.<sup>19</sup> Given its better safety profile, deflazacort is increasingly being considered a viable alternative to prednisolone in the treatment of INS in children.

Therefore, this study aimed to evaluate the effectiveness and safety of deflazacort in children with the initial episode of INS.

## METHODS

This randomized controlled trial was conducted in the Department of Pediatric Nephrology, NIKDU, Dhaka, Bangladesh, from June 2019 to January 2021. In this study, we included 83 children, aged 2 to 12 years, who had INS and visited the outdoor department and were admitted to the pediatric nephrology department of NIKDU. Patients were divided into two treatment groups – group A patients were prescribed prednisolone, and group B patients were prescribed deflazacort.

These are the following criteria are to be eligible for enrollment as our study participants.

### Inclusion criteria

Patients aged between 2-12 years old, and patients who visited the outpatient department and were admitted to the hospital with an initial episode of INS were included.

### Exclusion criteria

Patients with age <2 years and >12 years, patients with nephrotic syndrome due to a secondary cause: systemic disease; patients with congenital nephrotic syndrome; nephrotic syndrome with a typical presentation like persistent hypertension, hematuria, and azotemia; H/O of taking immunosuppressive agents for an initial episode in other places; and patients who refused to participate in the study were excluded.

## Intervention

Patients were randomly assigned to two groups using a simple lottery method. Group A received prednisolone, while group B received deflazacort. Initially, group A consisted of 42 patients, of whom 5 were lost to follow-up. Similarly, group B comprised 41 patients, with 4 patients lost during follow-up. Ultimately, 74 patients were included in the final analysis, with 37 patients in each group.

### Group A

Group A patients were prescribed prednisolone, initially at 2 mg/kg/day for 6 weeks (two or three divided doses), followed by 1.5 mg/kg/day on every alternate day for 6 weeks, as a single dose.<sup>19</sup> In cases of nephrotic syndrome, the therapeutic dosage ratio of deflazacort has been reported as 1:1.28.<sup>20</sup> Therefore, the above dosages are prescribed.

### Group B

Group B patients were prescribed deflazacort, initially at 2.4 mg/kg/day for 6 weeks (two or three divided doses). Then, they received 1.8 mg/kg on alternate days for 6 weeks (single dose).<sup>5</sup>

## Data collection procedure

Patients with an initial episode of INS were included in the study, a detailed history was taken, and a proper physical examination was performed to exclude any secondary cause of nephrotic syndrome. Detailed history and proper physical examination were done for each patient (age, sex, height, weight, appearance, temperature, pulse, respiratory rate, blood pressure, other systemic examination) and recorded on a data collection sheet. Routine investigation, such as complete blood count, urine routine microscopic examination, and urine culture, Spot urinary protein, Creatinine ratio/24 hours urinary total protein. Serum cholesterol, serum albumin, serum creatinine, serum HBsAg, Mantoux test (MT test), and X-ray chest were done to confirm diagnosis and to exclude infection before starting treatment. Parents were counseled regarding drug compliance and toxicity. Informed written consent was taken from the legal guardians after selection, and particulars of the patients were recorded on a case recording sheet.

## Statistical analysis

All data were recorded systematically in a pre-formatted data collection form. Quantitative data was expressed as mean and standard deviation, and qualitative data was expressed as frequency distribution and percentage. Continuous variables were compared through an unpaired t-test, Mann-Whitney U-test, and categorical variables were analyzed by a Chi-square test. A p value <0.05 was considered significant. Statistical analysis was performed

by using statistical package for the social sciences (SPSS) 22 for Windows version 10. This study was ethically approved by the Institutional Review Committee of NIKDU, Dhaka, Bangladesh.

## RESULTS

This randomized controlled trial initially included 83 children, aged 2 to 12 years, with INS. Patients were randomly assigned to two groups using a simple lottery method. Group A received prednisolone, while group B received deflazacort. Initially, group A consisted of 42 patients, of whom 5 were lost to follow-up. Similarly, group B comprised 41 patients, with 4 patients lost during follow-up. Ultimately, 74 patients were included in the final analysis, with 37 patients in each group.

Table 1 presents the demographic characteristics of the study subjects. The mean age was significantly higher in group B ( $4.97 \pm 2.11$  years) compared to group A ( $3.87 \pm 1.23$  years), with a statistically significant p value of 0.007. No statistically significant differences were observed between the groups in terms of gender distribution, residence (rural versus urban), monthly family income, or parental education level. Most subjects resided in rural areas (81.1% versus 64.9%) and had a family income of 10,000–25,000 (54.1% versus 45.9%) in groups A and B, respectively. The majority of parents had at least a high school education (35.1% versus 48.6%) in groups A and B, respectively.

**Table 1: Sociodemographic characteristics of the respondents (n=74).**

| Characteristics        | Group A<br>(n=37), N<br>(%) | Group B<br>(n=37), N<br>(%) | P<br>value |
|------------------------|-----------------------------|-----------------------------|------------|
| Age (years)            |                             |                             |            |
| <5                     | 21 (56.8)                   | 23 (62.2)                   | 0.007      |
| 5-10                   | 13 (35.1)                   | 13 (35.1)                   |            |
| >10                    | 3 (8.1)                     | 1 (2.7)                     |            |
| Mean±SD                | 3.87±1.23                   | 4.97±2.11                   |            |
| Gender                 |                             |                             |            |
| Male                   | 19 (51.4)                   | 22 (59.5)                   | 0.486      |
| Female                 | 18 (48.6)                   | 15 (40.5)                   |            |
| Residence              |                             |                             |            |
| Rural                  | 30 (81.1)                   | 24 (64.9)                   | 0.119      |
| Urban                  | 7 (18.9)                    | 13 (35.1)                   |            |
| Monthly family income  |                             |                             |            |
| <10,000                | 4 (10.8)                    | 5 (13.5)                    | 0.780      |
| 10,000–25,000          | 20 (54.1)                   | 17 (45.9)                   |            |
| >25,000                | 13 (35.1)                   | 15 (40.5)                   |            |
| Parent education       |                             |                             |            |
| Primary                | 9 (24.3)                    | 7 (18.9)                    | 0.412      |
| High school            | 13 (35.1)                   | 18 (48.6)                   |            |
| College and university | 12 (32.4)                   | 7 (18.9)                    |            |
| No education           | 3 (8.1)                     | 5 (13.5)                    |            |

Table 2 shows that no statistically significant differences were observed between the two groups. Mean height, weight, and body mass index (BMI) were comparable, with p values of 0.513, 0.418, and 0.592, respectively. Systolic and diastolic blood pressure, as well as random blood sugar (RBS) and serum total cholesterol levels, also showed no significant differences (all  $p > 0.05$ ) between the two groups.

**Table 2: Baseline characteristics of the study patients (n=74).**

| Baseline characteristics               | Group A (n=37) | Group B (n=37) | P value |
|----------------------------------------|----------------|----------------|---------|
| <b>Height (cm)</b>                     | 99.27±13.82    | 101.66±17.28   | 0.513   |
| <b>Weight (kg)</b>                     | 15.78±4.91     | 16.86±6.42     | 0.418   |
| <b>BMI (kg/m<sup>2</sup>)</b>          | 15.68±1.65     | 15.90±1.85     | 0.592   |
| <b>Blood pressure (systolic)</b>       | 90.54±10.66    | 94.05±9.71     | 0.143   |
| <b>Blood pressure (diastolic)</b>      | 63.92±5.79     | 64.59±6.28     | 0.632   |
| <b>RBS (mmol/l)</b>                    | 5.36±1.01      | 5.40±0.81      | 0.867   |
| <b>Serum total cholesterol (mg/dl)</b> | 420.70±88.69   | 401.56±87.31   | 0.356   |

Group A=Prednisolone, group B=deflazacort

Table 3 compares the time required to induce remission and the incidence of relapse between group A (prednisolone) and group B (deflazacort). The mean time to achieve remission was significantly shorter in group B (7.87±3.33 days) compared to group A (9.82±3.43 days), with a statistically significant p value of 0.02. Although group A showed a higher percentage of relapses at both 3 months (10.8% versus 2.7%) and 6 months (16.2% in both groups), these differences were not statistically significant. The total relapse rate after 6 months was higher in group A (27.0%) than in group B (18.9%), but again, the difference did not reach statistical significance ( $p=0.41$ ).

**Table 3: Comparison between the time required to induce remission and the number of relapses in both groups (n=74).**

| Time                                      | Group A (n=37) | Group B (n=37) | P value |
|-------------------------------------------|----------------|----------------|---------|
| <b>Time to induce remission (mean±SD)</b> | 9.82±3.43      | 7.87±3.33      | 0.02    |
| <b>Relapse</b>                            | <b>n (%)</b>   | <b>n (%)</b>   |         |
| After 3 months                            | 4 (10.8)       | 1 (2.7)        | 0.17    |
| After 6 months                            | 6 (16.2)       | 6 (16.2)       | 1.00    |
| Total after 6 months                      | 10 (27.0)      | 7 (18.9)       | 0.41    |

Group A=Prednisolone, group B=deflazacort

Table 4 shows that no cases of moon face or buffalo hump were observed in either group at baseline or 3 months, except for 2 subjects (5.4%) in group A who developed

buffalo hump by 3 months. By the end of 6 months, both complications appeared more frequently in group A than in group B, with 29.7% of group A experiencing moon face and buffalo hump compared to 16.2% in group B. However, these differences were not statistically significant ( $p > 0.05$ ).

**Table 4: Complications of study subjects during follow-up (n=74).**

| Complications       | Group A (n=37), N (%) | Group B (n=37), N (%) | P value |
|---------------------|-----------------------|-----------------------|---------|
| <b>Moon face</b>    |                       |                       |         |
| On admission        | 0 (0.0)               | 0 (0.0)               |         |
| After 3 months      | 0 (0.0)               | 0 (0.0)               |         |
| After 6 months      | 11 (29.7)             | 6 (16.2)              | 0.443   |
| <b>Buffalo hump</b> |                       |                       |         |
| On admission        | 0 (0.0)               | 0 (0.0)               |         |
| After 3 months      | 2 (5.4)               | 0 (0.0)               | 0.395   |
| After 6 months      | 11 (29.7)             | 6 (16.2)              | 0.443   |

Group A=Prednisolone, group B=deflazacort

Table 5 presents a comparison of height and weight changes in the study subjects (N=74), divided equally into group A (prednisolone) and group B (deflazacort). Measurements were taken at baseline (on admission), after 3 months, and after 6 months. Both height and weight showed a gradual increase over time in both groups. Although group B exhibited slightly higher increases in both parameters, the differences between the two groups at each time point were not statistically significant (p value  $> 0.05$ ), indicating that neither prednisolone nor deflazacort led to significantly different growth outcomes over the 6-month follow-up period.

**Table 5: Comparison of height and weight of the study subjects (n=74).**

| Parameter          | Group A (n=37) | Group B (n=37) | P value |
|--------------------|----------------|----------------|---------|
| <b>Height (cm)</b> |                |                |         |
| On admission       | 99.27±13.82    | 101.66±17.28   | 0.513   |
| After 3 months     | 99.73±13.28    | 102.86±16.92   | 0.378   |
| After 6 months     | 100.95±13.22   | 104.16±16.88   | 0.365   |
| <b>Weight (kg)</b> |                |                |         |
| On admission       | 15.78±4.91     | 16.86±6.42     | 0.418   |
| After 3 months     | 16.14±4.84     | 17.11±6.25     | 0.456   |
| After 6 months     | 17.08±5.05     | 17.73±6.15     | 0.622   |

Group A=Prednisolone, group B=deflazacort

Table 6 shows that both systolic and diastolic BP values remained relatively stable within each group across the



three time points—on admission, after 3 months, and after 6 months. Although group B demonstrated slightly higher systolic BP values at each time point compared to group A, these differences were not statistically significant. Similarly, diastolic BP showed minimal variation between the groups, with no statistically significant differences observed (all p values >0.05).

**Table 6: Changes in blood pressure (N=74).**

| Parameter                  | Group A<br>(n=37) | Group B<br>(n=37) | P<br>value |
|----------------------------|-------------------|-------------------|------------|
| <b>Systolic BP (mmHg)</b>  |                   |                   |            |
| On admission               | 90.54±10.66       | 94.05±9.71        | 0.143      |
| After 3 months             | 91.88±8.11        | 93.06±6.54        | 0.525      |
| After 6 months             | 90.33±6.45        | 95.33±7.87        | 0.139      |
| <b>Diastolic BP (mmHg)</b> |                   |                   |            |
| On admission               | 63.92±5.79        | 64.59±6.28        | 0.632      |
| After 3 months             | 65.00±4.93        | 65.48±3.50        | 0.698      |
| After 6 months             | 65.83±5.27        | 65.50±3.26        | 0.558      |

Group A=Prednisolone, group B=deflazacort

Table 7 presents the changes in serum cholesterol and random blood sugar (RBS) levels among study subjects over a 6-month follow-up period. Both groups showed a marked reduction in cholesterol levels from baseline to 3 months, with a mild increase observed by 6 months. Despite these trends, the intergroup differences at all the time points were not statistically significant ( $p>0.05$ ). Similarly, RBS levels remained within a narrow range across both groups throughout the study. Slight increases in RBS were noted over time in both groups, particularly in group A, but the differences between groups were not statistically significant at any interval.

**Table 7: Changes in cholesterol and random blood sugar (N=74).**

| Parameter                  | Group A<br>(n=37) | Group B<br>(n=37) | P<br>value |
|----------------------------|-------------------|-------------------|------------|
| <b>Cholesterol (mg/dl)</b> |                   |                   |            |
| On admission               | 420.70±88.69      | 401.56±87.31      | 0.35       |
| At 3 months                | 182.55±55.83      | 176.41±57.45      | 0.64       |
| At 6 months                | 202.53±81.71      | 210.17±106.72     | 0.73       |
| <b>RBS (mmol/l)</b>        |                   |                   |            |
| On admission               | 5.36±1.01         | 5.40±0.81         | 0.85       |
| At 3 months                | 5.69±1.07         | 5.40±1.16         | 0.27       |
| At 6 months                | 5.82±0.59         | 5.60±0.78         | 0.18       |

Group A=Prednisolone, group B=deflazacort

## DISCUSSION

Several studies have compared the efficacy and safety profile of deflazacort and prednisolone in the management of INS. Given the limited data demonstrating clear superiority of deflazacort over other commonly used oral steroids, the present study was undertaken to compare the

efficacy and safety of deflazacort in children with INS. A previous study by Penaloza et al observed that deflazacort was associated with milder side effects than prednisolone during the management of the first episode of INS.<sup>14</sup> Similarly, Broyer et al also previously concluded that deflazacort was more effective than prednisolone in reducing relapses in steroid-dependent INS.<sup>16</sup>

This randomized controlled trial was conducted in children experiencing their first episode of idiopathic nephrotic syndrome, aiming to assess the effectiveness and safety profile of deflazacort. Results showed that the mean time to achieve remission was significantly shorter in the deflazacort group ( $7.87\pm3.33$  days) compared to the prednisolone group ( $9.82\pm3.43$  days), with a statistically significant difference ( $p=0.025$ ). These findings align with those of Ravish et al, who reported a shorter remission time with deflazacort ( $10.25\pm2.4$  days) than with prednisolone ( $12.55\pm1.44$  days), with the difference also being statistically significant ( $p=0.012$ ).<sup>19</sup> Therefore, deflazacort appears to be more effective in inducing early remission in children with INS.

During the follow-up period in this study, relapses occurred in 3 patients (8.1%) in group A (prednisolone) and 1 patient (2.7%) in group B (deflazacort); however, this difference was not statistically significant ( $p=0.49$ ). Broyer et al found a significantly higher number of relapses in the prednisolone group ( $2.8\pm1.8$ ) compared to the deflazacort group ( $0.9\pm1.4$ ) ( $p=0.002$ ).<sup>16</sup> Similarly, Ravish et al reported a non-significant difference in relapse rates (1 in the deflazacort group and 3 in the prednisolone group,  $p=0.58$ ).<sup>19</sup>

Weight gain over six months of follow-up was greater in the prednisolone group (from  $15.78\pm4.91$  kg to  $17.08\pm5.05$  kg) compared to the deflazacort group (from  $16.86\pm4.42$  kg to  $17.73\pm6.15$  kg), though this difference was not statistically significant ( $p=0.04$ ). Broyer et al also reported a higher mean weight gain in the prednisolone group ( $3.9\pm4.1$  kg) compared to the deflazacort group ( $1.7\pm2.8$  kg), though this was not statistically significant.<sup>16</sup> Glucocorticoid-associated weight gain is typically attributed to increased appetite and fat deposition. Kurt et al reported that deflazacort leads to less fat accumulation than prednisolone.<sup>17</sup>

In this study, 61.3% of patients in group A (prednisolone) and 52.9% in group B (deflazacort) remained relapse-free during follow-up. However, Catarina et al reported that a significantly higher number of patients remained relapse-free in the prednisolone group (14 patients) compared to the deflazacort group (1 patient), with a p value <0.001.<sup>21</sup> This contrasts with the findings of the present study.

Growth parameters also favored deflazacort. In our study, height increased in both groups: from  $99.27\pm13.82$  cm to  $100.95\pm13.22$  cm in the prednisolone group and from  $101.66\pm17.28$  cm to  $104.16\pm16.88$  cm in the deflazacort group. Although the increase was greater in the deflazacort

group, the difference was not statistically significant ( $p=0.365$ ). A study by Lee et al reported that deflazacort therapy was associated with a lesser decline in growth velocity and improved stature over one to two years.<sup>15</sup>

Cushingoid features were less frequent in the deflazacort group. Moon face developed in 20% of patients in the deflazacort group compared to 36.7% in the prednisolone group. Buffalo hump was observed in 13.5% of group A and 11.8% of group B. While these differences were not statistically significant, they are consistent with findings by Ravish et al and Catarina et al, who also observed more cushingoid features in the prednisolone group.<sup>19,21</sup> Jat and Khairwa also reported that deflazacort was equally effective in inducing remission, with fewer relapses and a lower incidence of cushingoid symptoms compared to prednisolone ( $p<0.002$ ).<sup>12</sup> A study by Visal et al compared adverse drug reactions (ADRs) between the two drugs and reported a higher incidence with prednisolone (2.41%) compared to deflazacort (1.28%).<sup>22</sup>

Regarding lipid profiles, Kurt et al found no baseline differences between the two groups. However, during follow-up, significant increases in total cholesterol, HDL, and LDL were observed in both groups ( $p<0.001$ ), with greater elevations in the prednisolone group for total cholesterol ( $p<0.03$ ), LDL ( $p<0.01$ ), and lipoprotein B2 ( $p<0.03$ ). Triglyceride levels increased in the prednisolone group and decreased slightly in the deflazacort group ( $p<0.05$ ).<sup>17</sup> In contrast, our study did not find significant differences in serum cholesterol between the groups at baseline or during follow-up.

A study by Luca et al reviewed deflazacort's pharmacologic profile and noted its high anti-inflammatory and immunosuppressive activity, along with a favorable effect on glucose and calcium metabolism, growth, and hypothalamic-pituitary axis. Its broad therapeutic index allows for dosing flexibility ranging from 6 to 90 mg/day, depending on disease severity.<sup>23</sup>

### Limitations

Our study was a single-center study. We took a small sample size due to the short study period. After evaluating those patients, we did not follow up with them for the long term and did not know other possible interference that may happen in the long term with these patients.

### CONCLUSION

The findings indicate that both medications were effective in inducing remission; however, deflazacort demonstrated a significantly shorter time to remission compared to prednisolone in children with an initial episode of INS. Although relapse rates were slightly lower in the deflazacort group, the differences were not statistically significant. Deflazacort was associated with fewer side effects and overall showed a more favorable profile regarding growth parameters, blood pressure, cholesterol,

and blood glucose levels over the 6-month follow-up period, with no significant differences. The study suggests that it may be a suitable and well-tolerated alternative to prednisolone as a first-line therapy in pediatric INS. Further study with a prospective and longitudinal study design, including a larger sample size, needs to be done to validate the findings of our study.

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