



**2<sup>nd</sup>**  
Edition

# Algorithms *in* Pediatrics

*Editors*

**Anand S Vasudev • Nitin K Shah**

*Foreword*

**Vasant Khalatkar**



# Algorithms in **PEDIATRICS**

**Second Edition**

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## *Foreword*

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# Nephrotic Syndrome in Children

Mukta Mantan, Anand S Vasudev

## INTRODUCTION

Nephrotic syndrome is a common chronic disorder in children, characterized by heavy proteinuria ( $>40$  mg/ $\text{m}^2/\text{h}$  in timed urine sample), hypoalbuminemia, and edema. The proteinuria in nephrotic syndrome is relatively selective and constitutes primarily of albumin. The peak incidence of the disease is in between 2 and 6 years of age. 90% of the children with minimal change disease respond to treatment with steroids. Majority of these relapse and about 50–60% become steroid-dependent or frequent relapsers. Frequency of relapses is higher in first 10 years after the diagnosis. By puberty, the relapse rate decreases and most children show sustained remission.

Some common definitions to describe the course of nephrotic syndrome are listed in **Table 1**.

The most common etiology of childhood nephrotic syndrome is minimal change disease. The other glomerular etiologies causing nephrotic syndrome are focal segmental glomerular sclerosis, mesangioproliferative glomerulonephritis, membranoproliferative glomerulonephritis, and membranous nephropathy.

## EVALUATION

The primary evaluation of a child with suspected nephrotic syndrome includes estimation of serum total proteins, albumin, globulin, cholesterol, urea, and creatinine concentrations. Urinary proteins can be estimated with dipsticks. Values of  $>+3$  proteins are indicative of nephrotic range proteinuria. Urinary spot samples can be used for determining the urinary protein or creatinine ratio. Values beyond 2 are suggestive of nephrotic range proteinuria. Hepatitis B status should be determined if the child is unimmunized. Serum complement (C3) levels are recommended if persistent hematuria or hypertension occurs. Acute infections should be ruled out; latent or active tuberculosis too should be identified before starting

**TABLE 1:** Definitions.

| Terms                                          | Definitions                                                                                                                                                            |
|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Nephrotic syndrome                             | Presence of edema, serum albumin $<3.0$ g/dL and proteinuria $>40$ mg/ $\text{m}^2/\text{h}$ in timed urine sample or urine spot (mg/mg) Up/Uc $>2$                    |
| Relapse                                        | Urine protein $\geq 3$ by dipstick or Up/Uc $>2$ mg/mg for 3 consecutive early morning samples having been in remission previously                                     |
| Remission                                      | Urine protein nil or trace by dipstick or Up/Uc $<0.2$ mg/mg for 3 consecutive early morning samples                                                                   |
| Frequent relapses                              | Two or more relapses in 6 months of initial response or $>3$ in 6 months or $>4$ in any 12-month period                                                                |
| Steroid dependence                             | Occurrence of 2 consecutive relapses during steroid therapy or within 2 weeks of its cessation in absence of infections                                                |
| Steroid-resistance                             | Failure to achieve remission after 6 weeks of daily therapy of steroids (prednisolone oral) 2 mg/kg/day                                                                |
| Initial resistance                             | Failure to achieve complete remission after 6-week initial therapy with prednisolone                                                                                   |
| Late resistance                                | Initially, steroid-sensitive and develops steroid resistance in any subsequent relapse                                                                                 |
| Calcineurin (CNI)-resistant nephrotic syndrome | Nonresponse to cyclosporine or tacrolimus, given in adequate doses and titrated to optimal blood trough levels, for 6-month                                            |
| Complicated relapse                            | Relapse associated with life-threatening complications like hypovolemia requiring admission, serious infection (peritonitis, cellulitis, and meningitis) or thrombosis |

(Up/Uc: urinary protein or creatinine ratio)

prednisolone. Investigations at first and subsequent relapses are provided in **Box 1**. Urine culture and sensitivity is indicated only if clinical features of urinary tract infection are there.

**BOX 1:** Investigations at first episode of nephrotic syndrome.

- Investigations
  - Urinalysis
  - Blood counts
  - KFT, serum proteins, albumin, globulin, and total cholesterol
  - CXR and tuberculin test
- Additional investigations*
  - C3, C4, ASLO, if hematuria and hypertension
  - HBSAg, anti HCV—if history of jaundice, liver disease
  - Usg (KUB), only if hematuria and renal vein thrombosis is suspected or planning renal biopsy
- Subsequent relapses*
  - KFT, serum albumin, total cholesterol
  - CBC if infection suspected

(ASLO: antistreptolysin O; CBC: complete blood count; CXR: chest X-ray; HBSAg: hepatitis B surface antigen; HCV: hepatitis C virus; KFT: kidney function test; KUB: kidney, ureter, and bladder X-ray)

## ■ INDICATIONS FOR RENAL BIOPSY

Renal biopsy is indicated for children with steroid-resistant nephrotic syndrome, gross or persistent microscopic hematuria, or persistent hypertension. Children with features suggestive of systemic lupus erythematosus, other secondary causes of nephrotic syndrome, or before starting calcineurin inhibitors should also be biopsied. Prolonged (>30–36 months) therapy with calcineurin inhibitors (CNI) or reduced kidney function during their use is also an indication.

## ■ MANAGEMENT

Management of nephrotic syndrome includes specific and supportive management (**Table 2**).

### Specific Management

#### *Treatment of the Initial Episode*

Indian Society of Pediatric Nephrology currently recommends that initial episode of nephrotic syndrome be treated with prednisolone at 2 mg/kg (maximum 60 mg) or 60 mg/m<sup>2</sup> in single or divided dose for 6 weeks followed by 1.5 mg/kg (maximum 40 mg) or 40 mg/m<sup>2</sup> single-morning dose on alternate days for next 6 weeks.

#### *Management of Relapse*

Identify and treat any infections present. Prednisolone is administered at a dose of 2 mg/kg/day until protein is nil or trace for 3 consecutive days followed by 1.5 mg/kg/day on alternate days for 4 weeks and then discontinued abruptly.

### *Frequent Relapser and Steroid-dependent*

Long-term alternate day oral prednisolone is the initial strategy. Prednisolone, initially at doses of 0.5–0.7 mg/kg on alternate days is administered followed by slow tapering to 0.2–0.3 mg/kg; these doses are given for prolonged periods of 6–12 months. Requirement of steroids at doses more than 0.7 mg/kg/day or having features of steroid toxicity need alternative agents. The commonly used steroid-sparing drugs are levamisole, mycophenolate mofetil (MMF), and alkylating agents (cyclophosphamide and chlorambucil). Calcineurin inhibitors like cyclosporine and tacrolimus are used sparingly for steroid-sensitive disease (**Flowchart 1**). Specific drug usage is given in **Table 2**.

### *Steroid-resistant Disease*

All patients with minimal change disease, focal segmental glomerulosclerosis, or mesangioproliferative changes on renal biopsy are treated with calcineurin inhibitors like cyclosporine and tacrolimus. The duration of treatment is at least 2–3 years for steroid-resistant disease. The response rate to these agents is about 70–80%. Intravenous steroids like methylprednisolone and dexamethasone have been used for prolonged periods in the past, but due to their poor response rates and high toxicity, their use is discouraged. Intravenous cyclophosphamide monthly pulses in doses of 500 mg/m<sup>2</sup> for 6 doses along with low-dose alternate day steroids have a response rate of about 50%. This drug can be used if the cost of calcineurin inhibitors is a constraint.

### Supportive Management

#### *Diet*

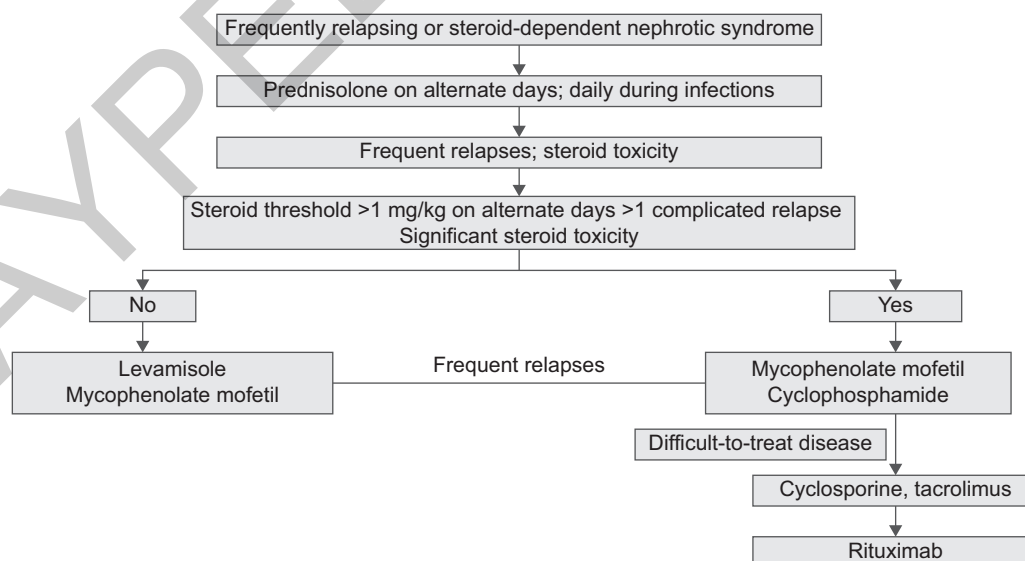
A balanced diet adequate in protein (1.5–2 g/kg) and calories is recommended. Fats should provide <30% calories, and saturated fats should be avoided. Salt restriction is advised only for patients with persistent edema or hypertension.

The initial strategy is to administer prednisolone at a dose of 0.5–0.7 mg/kg on alternate days. In patients with stable remission (sustained remission or infrequent relapses), therapy may be tapered to 0.2–0.3 mg/kg on alternate days for 6–12 months. Daily therapy at the same dose for 5–7 days, during minor infections, prevents infection-associated relapses. Patients who relapse at steroid threshold >0.7 mg/kg or show steroid toxicity require therapy with steroid-sparing medications (**Flowchart 1**). The choice of agents is based on disease

**TABLE 2:** Drugs used for treatment of steroid-sensitive nephrotic syndrome.

|                       | <b>Dosage and side effects</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Levamisole            | Immunomodulatory drug. Doses of 2–2.5 mg/kg/day on alternate days for 2–3 years. Low-dose alternate day prednisolone is coadministered. Side effects include neutropenia, rashes, cutaneous vasculitis, and gastrointestinal symptoms. Monitoring of total leukocyte counts recommended every 3–4 months. Available 50 mg/150 mg tablets                                                                                                                                                                                                                                                                                           |
| Cyclophosphamide      | It is administered at a dose of 2–2.5 mg/kg/day for 8–12 weeks. Prednisolone is coadministered at a dose of 1.5 mg/kg on alternate days for 4 weeks, followed by 1 mg/kg the following 8 weeks; steroid therapy tapered and stopped in 2–3 months. The drug should be started once child is in remission. Side effects include bone marrow suppression with leukopenia, hemorrhagic cystitis, alopecia, vomiting, and gonadal toxicity. Monitoring of total leukocyte counts is recommended every 2 weeks. Discontinue during infections and maintain hydration during therapy. Available as a 50 mg tablet                        |
| Mycophenolate mofetil | It is a purine antagonist. It is a prodrug that is rapidly hydrolyzed to its active metabolite mycophenolic acid in the liver. It is given in doses of 25–35 mg/kg/day in 2 doses (12 hourly) for prolonged periods (1–2 years). Side effects include gastrointestinal intolerance. The drug can also cause lymphopenia. Monitoring of counts and LFT should be done. Available as 250 mg/500 mg tablets                                                                                                                                                                                                                           |
| Cyclosporine          | It inhibits interleukin-2-driven T-cell activation. In SSNS, it is used in doses of 3–5 mg/kg (100–150 mg/m <sup>2</sup> ) in 2 divided doses for 1–2 years. For SRNS, duration of therapy is 2–3 years. Coadministration of low-dose corticosteroids is often required. Side effects includes nephrotoxicity, hypertension, and hypertrichosis. Monitor KFTs every 2–3 months. Kidney biopsy is recommended after 2–3 years of use to identify nephrotoxicity. While drug levels are recommended to monitor toxicity, finances often becomes a limitation. It is available as syrup (100 mg/mL) and capsules (25, 50, and 100 mg) |
| Tacrolimus            | It is given in doses of 0.1–0.2 mg/kg/day and available as 0.5 mg/1.0 mg/2.0 mg tablets. Side effects are nephrotoxicity, hyperglycemia, neurotoxicity, diarrhea. Cosmetic side effects are less with tacrolimus compared to cyclosporine. Monitoring of Hb1AC, lipid profile, uric acid, serum magnesium should be done every 3 months. It is available as 0.5, 1.0, and 2 mg capsules                                                                                                                                                                                                                                            |
| Rituximab             | It is a chimeric monoclonal antibody that inhibits CD20-mediated B lymphocyte proliferation and differentiation. It is used in severe steroid dependency. It is given at doses of 375 mg/m <sup>2</sup> as weekly infusion for 2–4 doses. Available in 100 mg/500 mg vials.                                                                                                                                                                                                                                                                                                                                                        |

(KFT: kidney function test; LFT: liver function tests; SRNS: steroid-resistant nephrotic syndrome; SSNS: steroid-sensitive nephrotic syndrome)

**Flowchart 1:** Management protocol for childhood nephrotic syndrome.

Source: Sinha A, Bagga A, Banerjee S, Mishra K, Mehta A, Agarwal I, et al; Expert Group of Indian Society of Pediatric Nephrology. Steroid Sensitive Nephrotic Syndrome: Revised Guidelines. Indian Pediatr. 2021;58(5):461-81.

severity, adverse effects, patient age, cost of therapy, and parental preference. Levamisole or MMF are preferred medications for mild disease. Patients with high steroid threshold ( $>1$  mg/kg on alternate days), complicated relapses, and those with significant steroid toxicity may be treated with MMF at higher doses (1,000–1,200 mg/m<sup>2</sup>/day) or cyclophosphamide. The use of cyclophosphamide is avoided in children  $<5$ –7-year-old and in peripubertal boys due to reduced efficacy and risk of gonadal toxicity, respectively. Patients who relapse despite therapy with two or more steroid-sparing agents (difficult-to-treat

steroid sensitive disease) are considered for therapy with calcineurin inhibitors, and failing that, rituximab. The use of rituximab is avoided in young children due to the risk of hypogammaglobulinemia.

### Edema

Judicious use of diuretics helps in controlling edema. A protocol of edema management is given in **Table 3**. Rapid diuresis can occur with synergistic therapy, resulting in hypovolemia and hypokalemia. Monitoring of electrolytes is recommended during diuretic therapy.

**TABLE 3:** Management of edema in nephrotic syndrome.

|                                                                                                                                                                        |                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Step 1                                                                                                                                                                 | Assess volume status*                                                                                                                                                                                                                                |
| Step 2a                                                                                                                                                                | If hypovolemia, give 5 or 20% albumin infusion**                                                                                                                                                                                                     |
| Step 2b                                                                                                                                                                | If normovolemia or hypervolemia, use furosemide 2–8 mg/kg/day. Add spironolactone 2–3 mg/kg/day at high doses of furosemide. Restrict sodium intake. If inadequate response, add metol zone (0.1–0.3 mg/kg/day) or hydrochlorothiazide 2–3 mg/kg/day |
| <i>In cases of ill-sustained response to above measures:</i>                                                                                                           |                                                                                                                                                                                                                                                      |
| Step 3                                                                                                                                                                 | Administer intravenous furosemide 2–3 mg/kg/day every 12 hours                                                                                                                                                                                       |
| Step 4                                                                                                                                                                 | Consider intravenous furosemide infusion 0.1–1.0 mg/kg/h if the intravenous bolus effect not sustained                                                                                                                                               |
| Step 5                                                                                                                                                                 | If significant edema persists, give 20% albumin infusion with intravenous furosemide over 4 hours                                                                                                                                                    |
| *Assess volume status clinically—monitor pulse and blood pressure. In patients with hypovolemia, blood urea may be elevated, fractional excretion of sodium $<0.2\%$ . |                                                                                                                                                                                                                                                      |
| **20% albumin may be diluted in normal saline or 5% dextrose to prepare 5% albumin if preparation unavailable                                                          |                                                                                                                                                                                                                                                      |
| Source: Vasudevan A, Mantan M, Bagga A. Management of edema in nephrotic syndrome. Indian Pediatr. 2004;41(8):787-95                                                   |                                                                                                                                                                                                                                                      |

**TABLE 4:** Complications of nephrotic syndrome and their management.

| Complication     | Management                                                                                                                                                                                                                                                                                                                                                                    |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Infections       | <ul style="list-style-type: none"> <li>Most common being peritonitis, cellulitis, and pneumonias</li> <li>Penicillin most effective</li> <li>Injectable third-generation cephalosporins and aminoglycosides are used in serious cases</li> <li>Duration of therapy is 7–10 days, more prolonged up to 14 days in sepsis</li> </ul>                                            |
| Thromboembolism  | <ul style="list-style-type: none"> <li>Ultrasound Doppler for diagnosis of deep vein thrombosis is useful</li> <li>Ventilation–perfusion scan helps in identification of pulmonary embolism</li> <li>Low molecular weight heparin + oral warfarin for 3 months duration or till relapse persists is used</li> <li>Aim INR between 2.5–3.0 when on warfarin therapy</li> </ul> |
| Hyperlipidemia   | <ul style="list-style-type: none"> <li>Dietary management with fat restriction</li> <li>No clear guidelines for use of statins in children</li> <li>Simvastatin and atorvastatin can be used in children with persistent hypercholesterolemia in steroid-resistant disease</li> </ul>                                                                                         |
| Hypertension     | <ul style="list-style-type: none"> <li>ACE inhibitors and ARBs are preferred drugs</li> <li>Beta-blockers and calcium channel blockers can be used additionally if not controlled</li> <li>Use diuretics if edema is present</li> </ul>                                                                                                                                       |
| Steroid toxicity | <ul style="list-style-type: none"> <li>Short stature, cataract, glaucoma, and hypertension features of toxicity</li> <li>Use alkylating and steroid-sparing agents like cyclophosphamide, levamisole, cyclosporine, and mycophenolate mofetil</li> </ul>                                                                                                                      |

(ACE: angiotensin-converting enzyme; ARB: angiotensin receptor blockers; INR, international normalized ratio)

The new ISPN guidelines recommend use of diuretics if the weight gain due to edema is moderate to severe (>7% body weight). Minimal edema does not need any treatment and once prednisolone is started most patients will go into remission within 5–7 days.

The complications of nephrotic syndrome and their management is given in **Table 4**.

### Vaccination

Most live and killed vaccines can be given to children with nephrotic syndrome if they are off steroids for >1 month. For patients on low-dose alternate-day steroids, live and killed vaccines can be administered. However, live vaccines are to be avoided for those on doses of steroids >1 mg/kg on alternate days. For patients on cyclophosphamide, live vaccines should be avoided for 3 months after therapy while for those on MMF, levamisole, or calcineurin inhibitors, the waiting is usually 1 month after stopping therapy. For patients who have received rituximab live vaccines should be administered after B-cell recovery (6–9 months). All routine vaccination should be done as per national schedule and varicella vaccine should be given to all children with nephrotic syndrome.

#### KEY POINTS

- Treatment with daily steroids for 6 weeks distinguishes steroid-sensitive from steroid-resistant nephrotic syndrome.
- Edema needs to be treated only if there is significant ascites, respiratory distress due to ascites or effusions, excoriation, and extrusion of fluid from the skin.

- Intravenous albumin is indicated for treatment of hypovolemia in nephrotic syndrome.
- Alternative agents like cyclophosphamide, levamisole, and MMF are used in patients having a frequently relapsing or dependent course.
- Calcineurin inhibitors along with low-dose alternate-day steroids are the first-line drugs for treatment of steroid-resistant disease.

### SUGGESTED READING

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