Apparent steroid resistance associated with prednisolone suspension

Sir,

An 18-month-old female child born of non-consanguineous parentage presented with mild periorbital puffiness but no hematuria, hypertension, skin rashes, joint swellings or organomegaly. Initial investigations were hemoglobin 13.8 g/dl, total leucocyte count 10.5 × 10^3/µl, platelets 6.19 × 10^3/µl. Serum albumin 1.9 g/dl, serum cholesterol 303 mg/dl, urine albumin 4+, spot urine protein creatinine ratio 13, serum creatinine 0.2 mg/dl. She was started on daily oral prednisolone suspension containing prednisolone sodium phosphate (5 mg/5 ml) in the dose of 2 mg/kg/day for a period of 4 weeks. She was compliant with the steroid therapy. Daily urine dipsticks showed persistent 2+ albuminuria. At the end of 4 weeks, she continued to have 2+ to 3+ albuminuria with urine protein creatinine ratio 9.16, serum albumin 2.6 g/dl and serum cholesterol 418 mg/dl. There was no intercurrent infection. Antinuclear antibody was negative and complements C3 142 mg/dl. Renal biopsy was being considered. Meanwhile, the oral prednisolone suspension was converted to equivalent dosage of oral prednisolone tablet. The tablet was crushed and administered orally for further period of 2 weeks in the daily dose of 2 mg/kg/day. The patient responded and had a sustained remission even while on alternate day steroid therapy which was gradually tapered.

Oral prednisolone suspension containing prednisolone sodium phosphate is routinely prescribed in infants with nephrotic syndrome for the ease of administration. However, there may be danger of under dosing with prednisolone suspension due to particle size related sedimentation and pH related instability.[1] This phenomenon is mentioned in the drug patents, product monograms and also in few case reports comparing dose uniformity of various steroid formulations in ophthalmic solutions.[1-3] The uniform redispersion of the active drug in the suspension may not be always guaranteed by manual shaking of the suspension just prior to use as seen in our case. This may result in lower bioavailability of the actual drug, incorrect dosing, continued proteinuria and false impression of steroid resistance requiring unnecessary renal biopsies and alternative immunosuppressive therapy. It is believed, that although there are many similar observations while managing pediatric nephrotic syndrome, these are not reported. This fact must be remembered before labeling any infant being treated with steroid suspension as steroid resistant. Clinical trials comparing different oral prednisolone salt suspensions (e.g., prednisolone sodium phosphate and prednisolone acetate) and ensuring finer particle size, better homogeneity, increased bioavailability of the drug and clinical response may be helpful in this regards.[3]

In conclusion, we need to be aware of such occasional apparent steroid resistance associated with prednisolone suspension while treating infantile nephrotic syndrome.

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Dr. Uma Ali, Bai Jerbai Wadia Hospital for Children, Mumbai.

K. P. Sathe

Division of Pediatric Nephrology, Dept of Pediatrics,
Aditya Birla Memorial Hospital, Pune, Maharashtra, India

Address for correspondence:
Dr. K. P. Sathe,
D-602, "Laurel", 'Greens Society',
opposite Pudumjee Paper Mills, Aditya Birla Hospital Marg,
Thergaon, Chinchwad, Pune - 411033, India.
E-mail: kiranpsathe@yahoo.co.in

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