Response to the letter from M.G. Coulthard

Christian Plank · Wolfgang Rascher

Received: 17 December 2008 / Accepted: 17 December 2008 / Published online: 7 February 2009
© IPNA 2009

We have read the letter of Dr. Coulthard with great interest [1]. Dr. Coulthard points out that a subgroup analysis of the remission rates in children with focal segmental glomerulosclerosis (FSGS) versus minimal change or mesangial proliferative histology indicates a benefit of cyclosporin A treatment only in children with FSGS. We agree on the point that this type of analytical approach provides an interesting inside look at the influencing factors for remission. Nevertheless, this prospective trial [2] was designed to test cyclosporin A versus cyclophosphamide in paediatric patients with newly diagnosed primary glucocorticoid resistance. The study was not planned and powered for histology, nor was the study planned to perform a subgroup analysis for FSGS. Stratification was done according to the contributing centres to control for centre-specific influences. Sample size calculation estimated that 60 patients needed to be enrolled in the study. Stratification according to histology had been discussed, but was not performed due to the small number of patients. Consequently, the number of children with FSGS was

higher in the cyclophosphamide arm (13/17) than in the cyclosporin A arm (8/15). This is most certainly a bias that must be considered in the interpretation of the results of the study. The unequal allocation of histological diagnosis and the small numbers compared in the analysis may be a reason why a better remission rate in FSGS patients on cyclosporin A was observed by Dr. Coulthard.

Since the protocol with high-dose immunosuppression is toxic, the protocol defined conditions for a premature termination of the trial. We agree that a significance level < 0.01 would have been scientifically more attractive, but due to the fact that this is a trial in severely ill children, the safety and well being of our patients was our major concern. Although the study had to be stopped prematurely, we hope the data of this study may provide valuable information to clinicians due to the exclusive selection of primary steroid-resistant patients and the direct comparison of cyclosporin A and cyclophosphamide.

References

1. Coulthard MG (2009) Which children with nephrotic syndrome benefit from cyclosporin A or cyclophosphamide? *Pediatr Nephrol* doi:10.1007/s00467-009-1127-8
2. Plank C, Kalb V, Hinkes B, Hildebrandt F, Gefeller O, Rascher W, Arbeitsgemeinschaft für Pädiatrische Nephrologie (2008) Cyclosporin A is superior to cyclophosphamide in children with steroid-resistant nephrotic syndrome—a randomized controlled multicentre trial by the Arbeitsgemeinschaft für Pädiatrische Nephrologie. *Pediatr Nephrol* 23:1483–1493

C. Plank (✉) · W. Rascher
Department of Paediatrics, Paediatric Nephrology,
University Hospital Erlangen,
Loschgestraße 15,
91054 Erlangen, Germany
e-mail: christian.plank@uk-erlangen.de