

Dextran-sulfate plasma adsorption lipoprotein apheresis in drug resistant primary focal segmental glomerulosclerosis patients: Results from a prospective, multicenter, single-arm intervention study

*Vinod Krishnappa¹, **Ronith Chakraborty**^{1,2}, Cheryl Sanchez-Kazi³, Alejandro Quiroga⁴, Katherine E. Twombly⁵, Robert Mathias⁶, Megan Lo⁷, Shefali Mahesh⁸, Julia Steinke⁹, Timothy Bunchman¹⁰, Joshua Zaritsky¹¹, Rupesh Raina^{1,2}*

¹Akron Nephrology Associates/Cleveland Clinic Akron General, Akron, OH, USA

²Department of Nephrology, Akron Children's Hospital, Akron, Ohio, USA

³Loma Linda University Children's Hospital, Loma Linda, CA, USA

⁴Spectrum Health (Helen De Vos Children's Hospital), Grand Rapids, MI, USA

⁵Medical University of South Carolina, Charleston, SC, USA

⁶Nemours Children's Hospital, Orlando, FL, USA

⁷Children's Hospital of Richmond at VCU, Richmond, VA, USA

⁸Department of Nephrology, Akron Children's Hospital, Akron, Ohio, USA

⁹Division of Pediatric Nephrology, Dialysis and Transplantation, Helen Devos Children's Hospital and Clinics, Grand Rapids, MI, USA.

¹⁰Pediatric Nephrology & Transplantation, Children's Hospital of Richmond, Virginia Commonwealth University, Richmond, VA, USA.

¹¹Nemours, A.I. duPont Hospital for Children, Wilmington, DE, USA

Background: Focal segmental glomerulosclerosis (FSGS) causes end stage renal disease (ESRD) in significant proportion of patients worldwide. Primary FSGS carries poor prognosis and management of FSGS patients, refractory to standard treatments or resistant to steroids, remains a major challenge. Lipoprotein apheresis is a therapeutic approach for drug resistant primary FSGS and post-renal transplant primary FSGS recurrence.

Objectives: To examine the safety and probable benefit of apheresis treatment using Liposorber® LA-15 system in patients with nephrotic syndrome (NS) in post renal transplant children.

Material and methods: Prospective, multicenter, single-arm intervention study using Liposorber® LA-15 system. Patients ≤21 years old with drug resistant or drug intolerant NS secondary to primary FSGS with glomerular filtration rate (GFR) ≥60 ml/min/1.73m² or post renal transplant patients ≤21 years old with primary FSGS associated NS were included in the study. Each patient had 12 dextran-sulfate plasma adsorption lipoprotein apheresis sessions for 9 weeks. Patients were followed up at 1, 3, 6, 12 and 24-months.

Results: Of 17 patients enrolled, six were excluded from the outcome analysis (protocol deviations). Three patients were lost to follow-up immediately after completion of apheresis. At 1-month follow-up, 1 of 7 patients (14.3%) attained partial remission of NS while 2 of 4 subjects (50%) and 2 of 3 subjects (66.7%) had partial/complete remission

at 3- and 6-months follow-up, respectively. One of two patients followed up for 12 months had complete remission and one patient had partial remission of NS after 24 months. Improved or stable eGFR was noted in all patients over the follow-up period.

Conclusion: Our study showed improvement in response rates to steroid or immunosuppressive therapy and induced complete or partial remission of proteinuria in some of the patients with drug resistant primary FSGS. The main limitation of our study was the small number of subjects and high dropout rate.