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A multicenter, randomized, open-label, comparative, phase IV study to evaluate the efficacy and safety of a combination treatment of mycophenolate mofetil and corticosteroid in advanced IgA nephropathy

Sang Youb Han², **Chan-Young Jung**¹, Sang Ho Lee³, Dong Won Lee⁴, Sik Lee⁵, Chan-Duck Kim⁶, Bum Soon Choi⁷, Beom Seok Kim¹

¹Department of Internal Medicine-Nephrology, Severance Hospital, Korea, Republic of

²Department of Internal Medicine-Nephrology, Inje University Sanggye Paik Hospital, Korea, Republic of

³Department of Internal Medicine-Nephrology, Kyung Hee University Medical Center, Korea, Republic of

⁴Department of Internal Medicine-Nephrology, Pusan National University Hospital, Korea, Republic of

⁵Department of Internal Medicine-Nephrology, Chonbuk National University Hospital, Korea, Republic of

⁶Department of Internal Medicine-Nephrology, Kyungpook National University Hospital, Korea, Republic of

⁷Department of Internal Medicine-Nephrology, The Catholic University of Korea, Seoul St. Mary's Hospital, Korea, Republic of

Objectives: It remains unclear whether immunosuppressive agents are effective in patients with IgA nephropathy (IgAN). We sought to determine the efficacy of mycophenolate mofetil (MMF) and corticosteroid combination therapy in patients with advanced IgAN.

Methods: We conducted a multicenter, randomized, placebo-controlled, parallel group study of a 48-week administration of MMF and corticosteroids in biopsy-proven advanced IgAN patients with an estimated glomerular filtration rate (eGFR) between 20-50 mL/min/1.73m² and a urine protein-to-creatinine ratio (UPCR) greater than 0.75g/day. The primary outcome was complete (UPCR<0.3g/day) or partial remission (reduction of UPCR >50% compared to baseline) at 48 weeks.

Results: Of the 48 randomized patients, complete and partial remission rates were higher in the MMF and corticosteroid combination therapy group (29.1% vs. 5.0%, *P*=0.05). In contrast to the combination therapy group, eGFR in the control group significantly decreased from 36 weeks onwards, resulting in a final adjusted mean change of -4.39 ± 1.22 mL/min/1.73m² (*P*=0.002). The adjusted mean changes at 48 weeks were 0.62 ± 1.30 and -5.11 ± 1.30 mL/min/1.73m² (*P*=0.005) in the treatment and control groups, respectively. The amount of UPCR was also significantly different between the two groups, where the adjusted mean difference was -0.47 ± 0.17 mg/mgCr in the treatment group and 0.07 ± 0.17 mg/mgCr in the control group (*P*=0.04). Overall adverse events did not differ between the groups.

Conclusions: In patients with advanced IgAN with a high risk for disease progression, combination therapy of MMF and corticosteroid appears to be beneficial in reducing proteinuria and preserving renal function.

Figure 1. Time course of the estimated glomerular filtration rate in each group. (A) Changes in estimated glomerular filtration rate. (B) Adjusted mean changes in estimated glomerular filtration rate.

Fig. 2

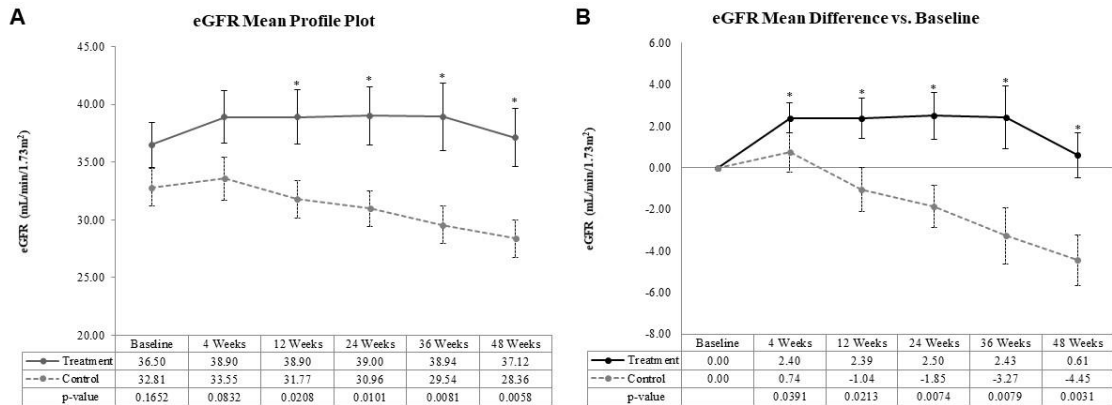


Figure 2. Time course of the urine protein-to-creatinine ratio in each group. (A) Changes in the urine protein-to-creatinine ratio. (B) Adjusted mean changes in the urine protein-to-creatinine ratio.

Fig. 3

