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Comparison of combination preemptive therapy of high-dose IVIG and rituximab versus rituximab in kidney transplant patients with subclinical de novo donor-specific antibodies: a randomized clinical trial

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Objectives: De novo donor-specific antibody (dDSA) is associated with the higher risk of kidney graft failure regardless of rejection events. However, there was no randomized clinical trial to evaluate the effectiveness of preemptive treatment for subclinical dDSA in kidney transplant (KT) patients. Therefore, we compared the combination therapy of high-dose intravenous immunoglobulin (IVIG) and rituximab with rituximab for subclinical dDSA.

Methods: A open label, randomized controlled clinical trial was conducted at two institutions (Severance Hospital and Seoul National University Hospital) in Korea. Adults (aged ≥19 years) KT patients with subclinical class II dDSA were enrolled between January 2019 and September 2020; follow-up ended August 2021. Eligible participants with mean fluorescent intensity ≥ 1,000 were randomly assigned to receive rituximab, or rituximab combined with IVIG at a ratio of 1:1. The primary end point was the change of titer of dDSA at 3 and 12 months after preemptive treatment.

Results: A total of 46 patients (24 received rituximab, and 22 received rituximab with IVIG) were finally included in the full analysis. The mean eGFR was 66.7 ± 16.3 mL/min/1.73 m^2, and the mean age was 48.9 ± 12.2 years at baseline. The titer decline of immune-dominant dDSA at 3 months in IVIG/rituximab group was significant compared to those of rituximab group (P = 0.041). However, there was no difference between two treatment groups at 12 months. Meanwhile, sum of class II dDSA titer and kidney function at 3, and 12 months did not show any difference between two groups. On the other hand, either treatment group showed significant decline of immune-dominant dDSA compared to no treatment group (n=53). No significant serious adverse drug reactions were detected among the enrolled patients.

Conclusions: Preemptive administration of high-dose IVIG combined with rituximab did not show a significant benefit in reducing dDSA compared to the administration of rituximab only.