KSN 2017 Abstract

KSN-17-O106

Minimal tacrolimus maintenance dosage with conventional use of enteric-coated mycophenolate sodium for stable kidney transplant recipients: A randomized controlled trial.

Sehoon PARK[1], Yon su KIM[1], Jungpyo LEE[3], Wooseong HUH[4], Chul woo YANG[5], Young-lim KIM[6], Yeong hoon KIM[7], Joong kyung KIM[8], Chang-kwon OH[9], *Su-kil PARK[2]

[1]Department of Biomedical Sciences, Seoul National University Hospital, Seoul National University College of Medicine, Korea,South, [2]Department of Internal Medicine, Asan Medical Center, University of Ulsan College of Medicine, Korea,South, [3]Department of Internal Medicine , Seoul National University Boramae Hospital, Seoul National University College of Medicine, Korea,South, [4]Department of Internal Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Korea,South, [5]Department of Internal Medicine, Seoul St. Mary's Hospital, The Catholic University of Korea College of Medicine, Korea,South, [6]Department of Internal Medicine, Kyungpook National University Hospital, Kyungpook National University School of Medicine, Korea,South, [7]Department of Internal Medicine, Busan Paik Hospital, Inje University College of Medicine, Busan, Korea,South, [8]Department of Internal Medicine, Bongseng Memorial Hospital, Korea,South, [9]Department of Surgery , Ajou University Hospital, Ajou University School of Medicine, Korea,South

Objectives : Minimizing tacrolimus dosage in patients with stable allograft function needs further evidence.

Methods : We performed an open-label randomized controlled study, from 2010 to 2016 in 7 tertiary teaching hospitals in Korea with 345 kidney transplant recipients who maintained stable graft status. The study group received reduced dose tacrolimus, 1,080-1,440 mg/day of enteric coated mycophenolate sodium (EC-MPS) and corticosteroid. The control group had standard tacrolimus dosage and 540-720 mg/day of EC-MPS with steroid. The primary endpoint was mean estimated glomerular filtration rate (eGFR) and eGFR change at the end of the study, 12 months after randomization.

Results : As a result, mean tacrolimus trough level of the study group was about 4.51±1.62 ng/mL, which was lower than that of the control group, 6.75±2.82 ng/mL (P<0.001). The primary endpoint was better in the study group in terms of eGFR change (P<0.001). The month 12 eGFR was 73.6±28.4 and 68.3±18.1 mL/min/1.73m2 in the study and the control group, respectively, but the difference did not reach level of statistical significance (P=0.066). Incidence of

adverse events was similar and there was no graft loss.

Conclusions : Therefore, minimizing tacrolimus level up to 4.5 ng/mL, combined with conventional EC-MPS, could be considered in patients on steady follow-up without increasing rejection risk.

Keywords : Kidney transplantation, tacrolimus, mycophenolate sodium, rejection