

Drug-drug interaction of potassium competitive acid blocker with tacrolimus and mycophenolate in kidney transplant recipients: a randomized controlled trial using smart clinical trial platform

Seong Wook Lee¹, Young-Hwan Lee¹, You Hyun Jeon¹, Jeong-Hoon Lim², Hee-Yeon Jung¹, Sun-Hee Park¹,
Chan-Duck Kim¹, Yong-Lim Kim¹, Jang-Hee Cho¹

¹Department of Nephrology, Kyungpook National University Hospital, Daegu, Korea

²Department of Nephrology, Kyungpook National University Chilgok Hospital, Daegu, Korea

Background: Potassium competitive acid blocker (P-CAB) is a newly developed gastric acid inhibitor exhibiting faster action and lower drug toxicity than proton pump inhibitor (PPI). The study aimed to compare the changes in the blood concentration of immunosuppressants after the administration of P-CAB.

Methods: A total of 62 kidney transplant recipients (KTRs) were randomized to either P-CAB (tegoprazan) or PPI group. A smart clinical trial platform monitored the enrolled patients with remote monitoring and safety management systems. Remote monitoring system transmitted data about drug adherence, blood pressure, body temperature, and electrocardiogram. Questionnaires for general and gastrointestinal (GI) symptoms were surveyed using a self-developed app installed on the patient's phone. One non-face-to-face video visit was scheduled during the study period. Trough levels of tacrolimus and mycophenolate were checked monthly for 3 months.

Results: Baseline characteristics including trough levels did not differ between groups. The adherence to the study medication was 100% in both groups. A total of 13,726 biometric information and 5,031 questionnaire answers were collected. We conducted 5,704 feedback messages and 56 non-face-to-face video visits. Mean trough levels of tacrolimus and mycophenolate did not differ between P-CAB and PPI groups at 3 months (5.5 ± 1.6 vs. 5.8 ± 2.0 ng/mL, $P=0.50$ and 2.7 ± 1.4 vs. 2.6 ± 1.4 ug/mL, $P=0.57$, respectively). The intragroup difference of the trough levels between baseline and 3 months was not significant in both groups. The average questionnaire scores of GI symptoms were comparable between groups. The vital signs and allograft function maintained stable without significant difference during the study period.

Conclusions: P-CAB does not affect the serum trough levels of tacrolimus and mycophenolate in KTRs. P-CAB showed a similar effect on the patient-reported GI symptoms compared to PPI. Our smart clinical trial system with non-face-to-face video visits demonstrated the efficacy and safety in performing randomized trials.

Corresponding author: Jang-Hee Cho

E-mail: jh-cho@knu.ac.kr

© The Korean Society for Transplantation

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/4.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.