

신장 이식 후 MMF에서 Myfortic로 전환 면역 억제 요법의 위장관 증상 호전 및 환자 만족도를 평가하기 위한 다기관 임상연구

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Effect of Conversion of Enteric Coated Mycophenolate Sodium to Mycophenolate Mofetil on Gastrointestinal Symptom and Quality of Life in Patients with Tacrolimus-based Immunosuppression

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Background: This study was performed to investigate the effects of conversion of mycophenolate mofetil (MMF) on enteric coated mycophenolate sodium (EC-MPS) to the improvement of GI symptoms and quality of life in patients with tacrolimus-based immunosuppression.

Methods: Two hundred and fifty eight patients received kidney transplant at least 3 months prior to study enrollment participated in this 4-week, prospective multi-center, open-labeled, comparative, longitudinal trial. On screening visit, GI symptom rating scale (GSRS) was measured and patients, who had less than 2 scores of GSRS, were requested for keeping MMF (n=83) and patients with GI symptoms (GSRS≥2) were converted to equimolar doses of EC-MPS (n=175). Changes in GI symptom burden were evaluated by GSRS and GIQLI (GI symptom-related quality life index). Overall treatment effect was evaluated by both patients and physicians.

Results: There was significant difference in overall patients GSRS (2.16 ± 0.84 in baseline vs. 1.98 ± 0.73 in month 1, $p < 0.001$) and GIQLI score (3.07 ± 0.48 in baseline vs. 3.17 ± 0.42 in month 1, $p < 0.001$) from baseline to month 1. The mean change in overall GSRS score from baseline was -0.18 ± 0.74 (-0.34 ± 0.79 , $p < 0.001$ for EC-MPS and 0.16 ± 0.47 , $p = 0.002$ for MMF). The mean change of overall GIQLI score from baseline was 0.10 ± 0.36 (0.17 ± 0.38 , $p < 0.001$ for EC-MPS and -0.05 ± 0.25 , $p = 0.085$ for MMF). Furthermore, significant change in GSRS and GIQLI subscale scores were also observed ($p < 0.05$). EC-MPS conversion group was considered that their symptoms had improved compared to baseline more than MMF group by overall treatment effect (patients: 40.0% vs. 8.4%, $p < 0.001$ and investigator: 45.1% vs. 9.6%, $p < 0.001$).

Conclusion: Conversion from MMF to EC-MPS is effective in improving GI symptom and quality of life in patients with tacrolimus-based immunosuppression.

Key Words: 마이폴릭, 위장관 증상, 신장이식 Enteric-coated mycophenolate sodium, kidney transplantation