

Change of GI Symptom and Quality of Life in Renal Transplant Patients after Conversion from Mycophenolate Mofetil (MMF) to Enteric coated Mycophenolate (EC-MPS)

Department of Nephrology¹ Sungkyunkwan Univ School of Medicine Samsung Medical Center, Department of General Surgery² Hallym Univ Kangdong Sacred Heart Hospital; Department of Nephrology³ Catholic Univ Kangnam St Mary's Hospital; Department of Nephrology⁴ Inje Uni Pusan Paik Hospital
Department of General Surgery⁵ Asan Medical Center; Department of Nephrology⁶ Seoul National Univ Hospital, Department of General Surgery⁷ Severance Hospital; Clinical Development and Medical⁸ Affairs Novartis Korea Ltd

오하영¹ · 이삼열² · 양철우³ · 김영훈⁴ · 한덕종⁵ · 김연수⁶ · 김명수⁷ · 하경수⁸

Change of GI Symptom and Quality of Life in Renal Transplant Patients after Conversion from Mycophenolate Mofetil (MMF) to Enteric coated Mycophenolate (EC-MPS)

Hayoung Oh¹, Samyel Lee², Chulwoo Yang³, Yeonghoon Kim⁴
Duckjong Han⁵, Yonsu Kim⁶, Myoungsoo Kim⁷ and Kyoungsoo Ha⁸

Department of Nephrology¹ Sungkyunkwan Univ School of Medicine Samsung Medical Center; Department of General Surgery² Hallym Univ Kangdong Sacred Heart Hospital; Department of Nephrology³ Catholic Univ Kangnam St Mary's Hospital; Department of Nephrology⁴ Inje Uni Pusan Paik Hospital; Department of General Surgery⁵ Asan Medical Center; Department of Nephrology⁶ Seoul National Univ Hospital; Department of General Surgery⁷ Severance Hospital; Clinical Development and Medical⁸ Affairs Novartis Korea Ltd

Objectives : The primary objective of this study is to identify if GI symptom severity and Health- related Quality of Life (HRQL) improve after patients are converted from Mycophenolate mofetil (MMF) to EC- MPS (Myfortic[®]) because of GI complaints. The secondary objective is to identify and evaluate the impact of immunosuppressive- induced GI symptoms on patient' s perception of symptom severity and HRQL.

Methods : This was a multi- center, open- label, longitudinal, comparable, observational study to characterize the impact that GI complaints have on patient- reported outcomes in patients who have had a renal transplant. Patients were evaluated at visit1 and then again after 4(+2) weeks (visit2). 172 patients who have received a kidney transplant who are experiencing GI complaints and are eligible to convert to EC- MPS (EC- MPS group) and 110 patients who have received a kidney transplant who are not experiencing GI complaints (MMF group). GI symptom and HRQL improvement was evaluated using Gastrointestinal Symptom Rating Scale (GSRS), Gastrointestinal Quality of Life Index (GIQLI), Psychological General Well- Being Index (PGWB), and Overall Treatment Effect Scale (OTE). The analysis of data was performed by two- sides test at type- I- error 5% for the intent- to treat analysis population and per protocol analysis population.

Results : GI complaints and Serious Adverse Events were 6 (2.13%) cases. Among this, EC- MPS group was 4 (2.37%) cases and MMF group was 2(1.77%) cases. Cases with related study drug was 2 (1.18%) of EC- MPS Group. Total scores of GSRS and HRQL (Change Median=5.00, 5.00, p- value=<0.0001, <0.0001, respectively) showed significant statistical improvement in EC- MPS group. There was no significant change in HRQL or GSRS in MMF group.

Conclusion : According to completed analysis of safety, HRQL and GI symptom severity were improved for patients with GI complaints converted from MMF to EC- MPS.

Key Words : EC- MPS, Renal Transplant, GI symptom