Drugs 2005; 65 (6): 806-807
0012-6667/05/0006-0806/$39.95/0

Mycophenolate Sodium Delayed Release

A Viewpoint by Maurizio Salvadori

Renal Unit, Careggi University Hospital, Florence, Italy

Mycophenolate sodium delayed release is an effective and safely used drug for the prevention of renal transplant rejection. This formulation of mycophenolate has a different pharmacokinetic profile, related to the release of the active agent in the small intestine, than that of mycophenolate mofetil.

Two fully published 1-year, double-blind studies that compared mycophenolate sodium delayed release with mycophenolate mofetil documented an equivalence both in efficacy and safety. Other studies using mycophenolate sodium delayed release (RAD 201, RAD 251 and an open-label extension[1] of a 1-year double-blind study) documented the safety of the drug over 36 months.

Although the most important primary and secondary endpoints did not reveal any significant difference between mycophenolate sodium delayed release and mycophenolate mofetil, dose changes due to gastrointestinal adverse events were slightly higher with mycophenolate mofetil in a large 1-year study in *de novo* renal transplant patients. Because of the clinical relevance of dose changes, prolonged studies enrolling a wider cohort of patients could better clarify possible differences between these two formulations.

The large myPROMS (myfortic prospective, multicentre study) is currently being conducted on different patient categories, with different drug combinations and will enrol 1800 patients. The results from this study could shed new relevant light on the positioning of mycophenolate sodium delayed release in the treatment of renal transplant recipients. ▲

Reference

1. Salvatori M, B301 Study Group. Long term administration of enteric-coated mycophenolate sodium (EC-MPS, myfortic) is safe in kidney transplant patients [abstract no. P194]. Transplantation 2004; 78 (2)