

## MYCOPHENOLIC ACID TROUGH LEVEL IN PATIENTS WITH IDIOPATHIC INFLAMMATORY MYOPATHIES – PILOT STUDY

*Tomasz Pawinski<sup>1</sup>, Anna Burdzy<sup>2</sup>, Piotr Szczęsny<sup>3</sup>*

<sup>1</sup> Department of Drug Chemistry, Pharmaceutical and Biomedical Analysis, Medical University of Warsaw, Banacha 1, 02-097 Warsaw, Poland

<sup>2</sup> Student Scientific Association, Department of Drug Chemistry, Pharmaceutical and Biomedical Analysis, Medical University of Warsaw, Banacha 1, 02-097 Warsaw, Poland

<sup>3</sup> Clinic and Polyclinic of Rheumatology, National Institute of Geriatric, Rheumatology and Rehabilitation, Spartanska 1, 02-645 Warsaw, Poland

**Background:** The aim of this study was to evaluate the association between mycophenolic acid trough level ( $C_0$ ) and disease activity in adult patients with idiopathic inflammatory myopathies (IIM). This study assessed the adherence, efficacy and safety profile of mycophenolate mofetil (MMF) during therapy. Due to its narrow therapeutic range, MPA concentrations monitoring has been developed for individual adjustment and is widely used in transplant patients, for whom it is established that pharmacokinetic parameters of MPA ( $C_0$ , AUC) correlates with the clinical outcome.

**Methods:** A prospective study was performed on a group of patients, who were on MMF therapy for a minimum period of 3 months. The study included 11 patients, with a male/female ratio 5:6. The medium of the age and body weight was 47.8 years and 70.6 kg respectively. MMF was used orally 2g BID, at a mean dose of 31.1 mg/kg. MPA concentrations was measured using a validated HPLC method developed in our laboratory. Active disease was defined as at least one of the activity domains: muscle activity (MMT8), worsening weakness or creatinine kinase ( $\geq 190$  U/L), myositis disease activity assessment tool (MDAAT) and in particular cases skin activity (CDASI).

**Results:** Mean MPA  $C_0$  was 1,9  $\mu\text{g/mL}$  (range: 0.38-4.37  $\mu\text{g/mL}$ ), and only 4/11  $C_0$  were above the 1.5  $\mu\text{g/mL}$  threshold. No difference in  $C_0$  for MPA was found between patients active and inactive disease (0.94 vs 0.98,  $p=0.7$ ). Also, no correlation has been noted between MMF dose and clinical outcome using Spearman's rank ( $r=0.06$ ,  $p=0.87$ ).

**Conclusions:** Neither in case MPA  $C_0$ , nor MMF dose any correlation with disease activity was found in idiopathic inflammatory myopathies. Due to the pilot nature of the study more prospective studies are still needed to assess usefulness of MPA monitoring during treatment patients suffering from IIM, as well as to control the impact of increasing MMF dose in IIM patients to improving clinical outcome.

**Key words:** idiopathic inflammatory myopathies, mycophenolic acid, therapeutic drug monitoring, mycophenolate mofetil, HPLC