**PP214—TACROLIMUS BLOOD CONCENTRATION IN PATIENTS SUBJECTED TO RENAL TRANSPLANTATION: THE INFLUENCE OF GENDER**

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**Introduction:** Tacrolimus, a potent immunosuppressant, is used for the prevention of allograft rejection in organ transplantation. Tacrolimus trough concentration (TTC) is still widely used as a guide to individual-izing tacrolimus dose requirements in renal transplantation. The aim was to investigate the effect of patient’s gender on TTC in renal transplant recipients on quaternary immunosuppressive therapy (tacrolimus, mycophenolate mofetil, prednisone, and anti-T lymphocyte globulin).

**Patients (or Materials) and Methods:** A PK study was conducted between October 2008 and December 2009 at MG hospital in Beirut, after IV GCV treatment in HSCT recipients with CMV infection. CMV disease was recognized by the combination of clinical signs and antigenemia. Patients received 1-hour infusion of 5 mg/kg q 12h for 14 days, and a complete PK study was performed at days 1, 7, and 14. A compartmental and no PK analysis were performed, and plasma GCV was analyzed by an HPLC validated method with UV detection. An ANOVA analysis associated to Friedman test was performed to compare the mean PK parameters. The 95% CI was calculated for some parameters and P < 0.05 was considered significant.

**Results:** Twelve patients were enrolled in this study. A significant difference in creatinine clearance (Ccr) and trombocytopenia, TTC (ng/mL) | Tacrolimus Trough Concentration (TTC), No. (%) | P value (Chi-square test)
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Male | Female | Male | Female | 0.0241
5 | 824 (25.3) | 497 (28.3) | 0.0027
5-10 | 1931 (59.3) | 1028 (58.5) | 0.6101
10 or more | 500 (15.4) | 231 (13.2) | 0.0386
500 or more | 3255 (100.0) | 1756 (100.0) | 0.0005

**Conclusion:** Our results indicated TTC as a useful guide in pointing out to potentially relevant influence of sex on its pharmacokinetics, what should be routinely considered and further studied.

**Disclosure of Interest:** None declared.

**PP215—PHARMACOKINETIC STUDY OF GANCICLOVIR (GCV) AFTER SINGLE AND MULTIPLE DOSE IN HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT) PATIENTS WITH CYTOMEGALOVIRUS (CMV) INFECTION**

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**Introduction:** Pharmacokinetic data of GCV are limited in HSCT patients under preemptive therapy and its induced hematologic toxicity still problematic. The aim of this study was to evaluate the PK of GCV after single and multiple doses in HSCT patients with CMV infection and to identify correlation between PK parameters and hematologic toxicity.

**Patients (or Materials) and Methods:** A PK study was conducted between October 2008 and December 2009 at MG hospital in Beirut, after IV GCV treatment in HSCT recipients with CMV infection. GCV was analyzed by an HPLC validated method with UV detection. An ANOVA analysis associated to Friedman test was performed to compare the mean PK parameters. The 95% CI was calculated for some parameters and P < 0.05 was considered significant.

**Results:** The relationship between lamotrigine serum concentration (µg/mL) and lamotrigine dose (mg/kg/d) were linear in both formulations (r² = 0.78484 original and r² = 0.83417 generic). There are statistically significant lower lamotrigine serum concentrations in patient treated with original formulation (3.97 [4.1] µg/mL) than those in patients treated with generic formulations (5.78 [2.7] µg/mL). No dose-dependent adverse effects appeared in the patients, though patients treated with generic drug were receiving higher doses due to assumption that they are less potent. Brand drug had a lower standard deviation (SD) and data scattering because, as the dissolution data showed, it is less influenced by pH changes. Further dissolution profiles of 2 formulations were only similar in pH 1.2 medium.

**Conclusion:** Investigation showed equal efficacy of 2 lamotrigine formulations, and the variations in plasma concentrations are probably due to individual characteristics of patients and differences in liberation rate of drugs in 2 formulations. It can be claimed that even if there are differences in dissolution profiles of 2 drugs they can have equal therapeutic efficacy.

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**Key words:** lamotriginedissolution profilegeneric formulation

**Disclosure of Interest:** None declared.