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POSTER PRESENTATION

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# Is there any relationship between the exposure to mycophenolic acid and the clinical status in children with lupus?

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## Background

The clinical benefit of Therapeutic Drug Monitoring (TDM) of mycophenolate mofetil (MMF) when used in children with lupus (SLE) has been scarcely studied.

## Aim

(i) To model mycophenolic acid (MPA; the active moiety of MMF) pharmacokinetic profiles (PK); (ii) to explore the relationships between exposure indices to MPA and the clinical status in paediatric inpatients with SLE receiving a maintenance immunosuppressive therapy including MMF.

## Methods

We launched a non-interventional study with analysis of clinical, biological and pharmacokinetic information. Full-PK profiles of MPA were modelled using an iterative two-stage approach (1). The clinical status was defined by the SLEDAI, the SLE being considered active for a score  $\geq 6$ . Relationships between MPA through concentrations ( $C_0$ ), AUC (Area Under Curve) or AUC/dose values, and the disease's activity were studied using logistic regression analysis.

## Results

Twenty six children (aged 10 to 17) with SLEDAI score from 0 to 20 (median: 4) followed-up in 5 French centres were included. High PK interpatient variability was observed:  $AUC_{0-12h} = 40.51 \pm 20.49$  mg.h/L. Trough concentrations ( $C_0$ ) were poorly correlated

analysis reported: (i) no relationship between  $C_0$  and SLEDAI; (ii) patients with an  $AUC_{0-12h}/\text{dose} < 0.058$  h/L were more likely to have an active disease (OR=4.8; 95CI: 0.9-25.0;  $p=0.067$ ).

## Conclusion

A tendency to a relationship between the lupus activity and the global MPA exposure was observed. Further data are needed to develop PK tools that could estimate the AUC using a limited sampling strategy and to lead prospective trials testing the clinical impact of a MMF TDM based on the AUC.

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## Reference

1. Saint-Marcoux F, et al: *Pharmacol Res* 2011.

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to the global exposure to MPA (AUC). Multivariate

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