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EXTERNAL VALIDATION OF POPULATION PHARMACOKINETIC MODELS OF HIGH DOSING METHOTREXATE IN PEDIATRIC PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA

Background and importance

High-dose methotrexate (HDMTX) as a **24h infusion** is essential to treat ALL

Monitoring methotrexate plasma concentrations must be performed to **prevent toxicities**

Aim and objectives

Evaluate the predictive ability of **two methotrexate pharmacokinetic models** in **pediatric oncology**

Material and Methods

2 pharmacokinetic models: A & B

Variables collected at 24-48h post-infusion (high risk patients 2-48h):

- ✓ **Individual prediction concentrations (Cipred)**
- ✓ **Methotrexate plasma concentrations (PCmtx)**
- ✓ Creatinine levels

Individual prediction error = *((Cipred – PCmtx)/PCmtx)*100*

Median of individual prediction error (MDIPE): Accuracy

Absolute median of individual prediction error (MAIPE): Precision

Goal: MDIPE ≤±10% & MAIPE ≤25%

Results

560 PCmtx from 57 patients with ALL (aged 2-17) received HDMTX 1-5 g/m^2

	MODEL A	MODEL B
24h	**MDIPE** = 6.7% (95%CI: 3.767-9.633) ✓ **MAIPE** = 8.7%	**MDIPE** = 31.1% (95%CI: 22.139-40.061) ✗ **MAIPE** = 31.1%
42h	**MDIPE** = -2.2% (95%CI: -8.608-4.208) ✓ **MAIPE** = 7.5%	**MDIPE** = 6.3% (95%CI: -0.771-13.371) ✓ **MAIPE** = 9.7%

Conclusion and Relevance

- **Model A**'s predictive ability is **higher at all times.**
- Model A exhibited **high accuracy** and **precision.**
- Model A proved to be **superior** and **more reliable.**