S-VEOIBD patients were considered those requiring intensified doses and frequencies during maintenance treatment to achieve IFX trough concentrations (Cmin) > 10 µg/ml.

THERAPEUTIC DRUG MONITORING OF INFLIXIMAB IN PAEDIATRIC SEVERE VERY EARLY-ONSET INFLAMMATORY BOWEL DISEASE

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BACKGROUND AND IMPORTANCE

Very early-onset inflammatory bowel disease (**VEOIBD**) (onset < 6 years), is a heterogeneous condition that tends to be refractory to conventional treatment. **Infliximab** (IFX) therapeutic drug monitoring (**TDM**) can guide high-dose therapy and improve response rates.

AIM AND OBJECTIVE

To assess the **effectiveness** and **safety** of **IFX** through a multidisciplinary **TDM** programme combined with **Bayesian forecasting** in **severe** VEOIBD (**S-VEOIBD**) patients compared to other children with inflammatory bowel disease (O-IBD).

MATERIALS AND METHODS

Ambispective single-centre study
Third-level hospital

Children with IBD treated with intravenous IFX

September 2015 - September 2023

S-VEOIBD patients were considered those requiring intensified doses and frequencies during maintenance treatment to achieve IFX trough concentrations (Cmin) > 10 µg/ml.

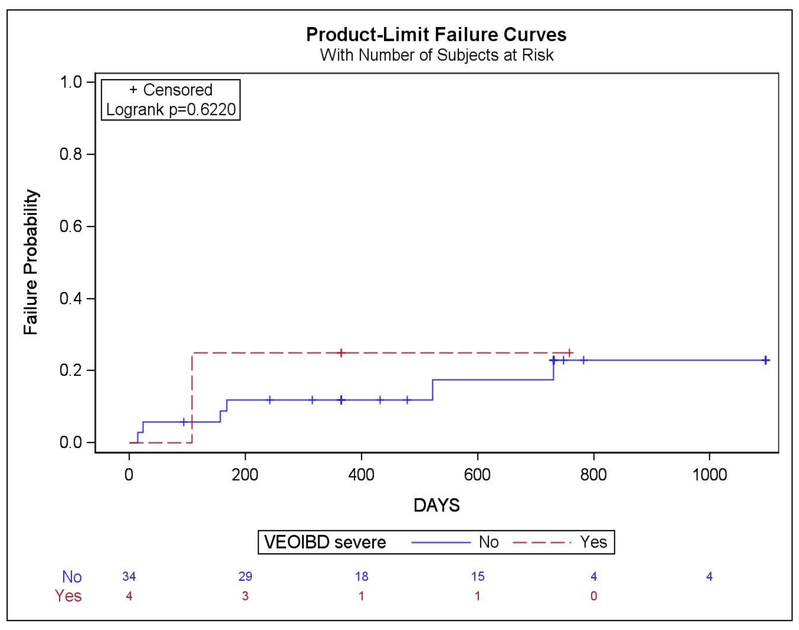
- **IFX Cmin** and anti-infliximab antibodies (**ATI**) were determined by **ELISA** or **chemiluminescence**.
- **Proactive TDM**: Dose individualisation → population pharmacokinetic model of **Fasanmade** *et a*l. (2011) → **NONMEM** v7.4.3. **IFX Cmin** was monitored at induction and every six months

We analysed: clinical, biological **remission, treatment failure (TF), hospitalisations, emergency visits and adverse drug reactions**.

RESULTS

Four (10.5%) patients were classified as **S-VEOIBD** and compared with **34 O-IBD** patients.

	s-VEOIBD	o-IBD	*P*-value
Age at diagnosis (years); median (IQR)	1.96 (1.01-2.99)	12.06 (9.78-14.53)	
Duration of follow up (years) median (IQR)	1.03 (0.84-1.45)	1.84 (1.08-2.54)	
Dosage (mg/kg), mean (SD)	10.27 (±2.37)	7.80 (±1.87)	
Frequency (weeks) (maintenance); mean (SD)	3.29 (±1.38)	6.50 (±1.62)	
At the end of Induction			
Cmin IFX (µg/mL), mean (SD)	16.11 (±5.42)	10.29 (±5.16)	0.07
Clinical Remission; n(%)	3 (75)	30 (88.24)	0.47
Biological Remission; n(%)	0 (0)	26 (76.47)	**<0.01**
C+B remission C+B; n(%)	0 (0)	25 (73.53)	**<0.01**
Treatment Failure; n(%):	0 (0)	2 (5.88): 1	0.50
At the end of 1st year (w=52)			
Cmin IFX (µg/mL), mean (SD)	12.13 (±8.68)	8.21 (±3.89)	0.52
Clinical Remission; n(%)	2 (50)	25 (80.65)	0.19
Biological Remission; n(%)	2 (50)	20 (64.52)	0.58
C+ B remission C+B; n(%)	2 (50)	20 (64.52)	0.58
Treatment Failure; n(%):	1 (25)	2 (6.45)	0.25



Kaplan–Meier cumulative probability curves for TF with IFX in children with s-VEOIBD vs O-IBD

- Hospitalisations (50.0% vs. 14.7%) and emergency visits (25.0% vs. 8.8%) were higher in S-VEOIBD.
- ARs were more common in S-VEOIBD (75.0% vs. 26.5%); 88.9% were infections and 11.1% infusion-related reactions.

CONCLUSION AND RELEVANCE

S-VEOIBD, compared with O-IBD patients, did not have higher cumulative probability of TF. Accelerated induction and maintenance drug monitoring with high Cmin can prevent TF in S-VEOIBD. High-dose regimens may be associated with a higher rate of ARs, mainly infectious.