REAL-WORLD EXPERIENCE IN HEMOPHILLIA B PATIENTS AFTER SWITCHING TO FIX EXTENDED HALF LIFE USING PHARMACOKINETIC POBLACIONAL SOFTWARE AND MONOCOMPARTIMENTAL MODEL

J.C. Juárez-Giménez 1, O. Benítez-Hidalgo 2, J.A. Romero-Garrido 1, C. Mateos-Salillas 3, S. González-Piñeiro 4, J.B. Montoro-Ronsano 1

1Pharmacy Service. Vall d’Hebron University Hospital, Barcelona, Spain. 2Hemophilia Unit. Vall d’Hebron University Hospital, Barcelona, Spain. 3Pharmacy Service. La Paz University Hospital. Madrid, Spain. 4Pharmacy Service. Da Coruña University Hospital. A Coruña, Spain.

Aim and objectives

Extended half-life recombinant Factor IX concentrations (rFIX-EHL) have improved the feasibility of the prophylaxis program and the quality of life of the treated Hemophilia B (HB) patients, since they dramatically increase the dosing interval and reduce the number of rFIX injections.

The efficiency of a pharmacokinetic-based tailored prophylaxis-dosing schedule versus standard dosing (DS) is compared, in HB, treated with two rFIX-EHL. Pharmacokinetics parameters were calculated.

Materials and methods

- Observational, analytical, prospective, multicentre study, involving HB patients, from three different hospitals, being treated with rFIX-EHL linked to albumin (rFIX-FP) or to fragment crystallizable (rFIX-Fc).
- Demographic and clinical data, and DS and dosing interval (DI) and actual FIX trough levels were recorded.
- Pharmacokinetic characterization was performed following both a population (WAPPS-HEMO) and a linear one-compartment (monocompartmental) approach. For each approach and rFIX preparation, an estimation of the time to the target trough (5 IU FIX/dL) was made. Statistical analysis was performed by means of the Student-Fischer t-test.

Background and Importance

The efficiency of rFIX-EHL treatment following a pharmacokinetic-based tailored prophylaxis-dosing schedule versus standard dosing (DS) is compared, in HB, treated with two rFIX-EHL. Pharmacokinetics parameters were calculated.

Results

The efficiency of rFIX-EHL treatment following a pharmacokinetic-based tailored prophylaxis-dosing schedule versus standard dosing (DS) is compared, in HB, treated with two rFIX-EHL. Pharmacokinetics parameters were calculated.

Conclusion and relevance

*The efficiency of rFIX-EHL treatment following a pharmacokinetic-based tailored prophylaxis-dosing schedule versus DS, in HB patients, is significantly higher. Depending on the commercial preparation, rFIX-FP or rFIX-Fc, the daily-adjusted dose, for a 5 IU FIX/dL trough target, ranges between 217 – 240 IU/day for rFIX-FP, or 450 – 508 IU/day for rFIXFc, according to the two pharmacokinetic approaches (individually and population based).

*There are differences between Cl and t ½ parameters when there were evaluated using the one-compartment model. rFIX-FP half life was longer (91h) versus rFIXFc half life (71.9h). No differences between rFIX-FP and rFIXFc was reported using the pharmacokinetic population software (WAPPS-HEMO)

**Table 1. Results how means (X) and standard deviation (±s) T: time , T5: Time with Cmin > 5% *11,9 days vs 13,6 days; p=0,12 ++ 14 days vs 10,2 days; p=0,012.

**Table 2. One-compartment model vs WAPPS-HEMO for rFIX-FP. Results how means (X) and standard deviation (±s)

**Table 3: One-compartment model vs WAPPS-HEMO for FIXFc. Results how means (X) and standard deviation (±s)