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Pharmacokinetic evaluation of extended half-life versus standard half-life factor VIII: Real-life conditions

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Topic: Epidemiology

INTRODUCTION

The use of extended half-life (EHL) factor VIII (FVIII) products is currently a strategy in patients with hemophilia A to improve disease control. In Latin America, there is limited evidence on the pharmacokinetics of EHL and standard half-life (SHL) medications.

AIM

To asses the area under the curve (AUC) and the times to reach specific coagulation factor levels in patients with hemophilia initially treated with SHL coagulation factors and later switched to EHL products.

METHOD

A retrospective study was conducted in a specialized outpatient care institution for hemophilia A. Patients initially treated with SHL factors (Beriate®, Immunate®, Octanate®, Advate®, Novoeight®, Hemophil M®, Xyntha®) and later switched to EHL (Adynovate® and Jivi®) were included. Pharmacokinetic (PK) parameters, such as AUC (IU*h/L) and the times to reach factor levels of 5%, 2%, and 1%, were evaluated. The half-life (T1/2) was calculated using the formula: Ln2/((Ln FVIII% T1 - Ln FVIII% T2) / (T2 - T1))(1), where T1 ≥ 4h and T2 ≥ 24h, using a population pharmacokinetic (PopPK) model based on the online medical platform WAPPS-Hemo®. Quantitative variables are presented as medians and interquartile ranges (IQR), while qualitative variables are shown as frequencies. Paired Willccox test was used with <0.05 as statistically significant differences.

RESULTS

Data collection **2019 - 2024**

29 Male patients

90% severe

10% moderate

44 PK to **SHL** — **PREVIOUS**

48 PK to **EHL** — **LATER**

A significant difference was found in the median AUC between SHL (7,208.5; IQR 6,198.4-9,066.6) and EHL (17,852.1; IQR 14,560.4-21,766.8), p<0.001. Significant differences were also found in the times to reach the 1% trough level (SHL: 58.2 h, IQR 50.8-74.1; EHL: 105.9 h, IQR 85.6-122.3; p<0.001). The T1/2 was longer in EHL medications (17.2 h, IQR 13.9 to 21.6) compared to SHL (10.7 h, IQR 8.5 to 13.9).

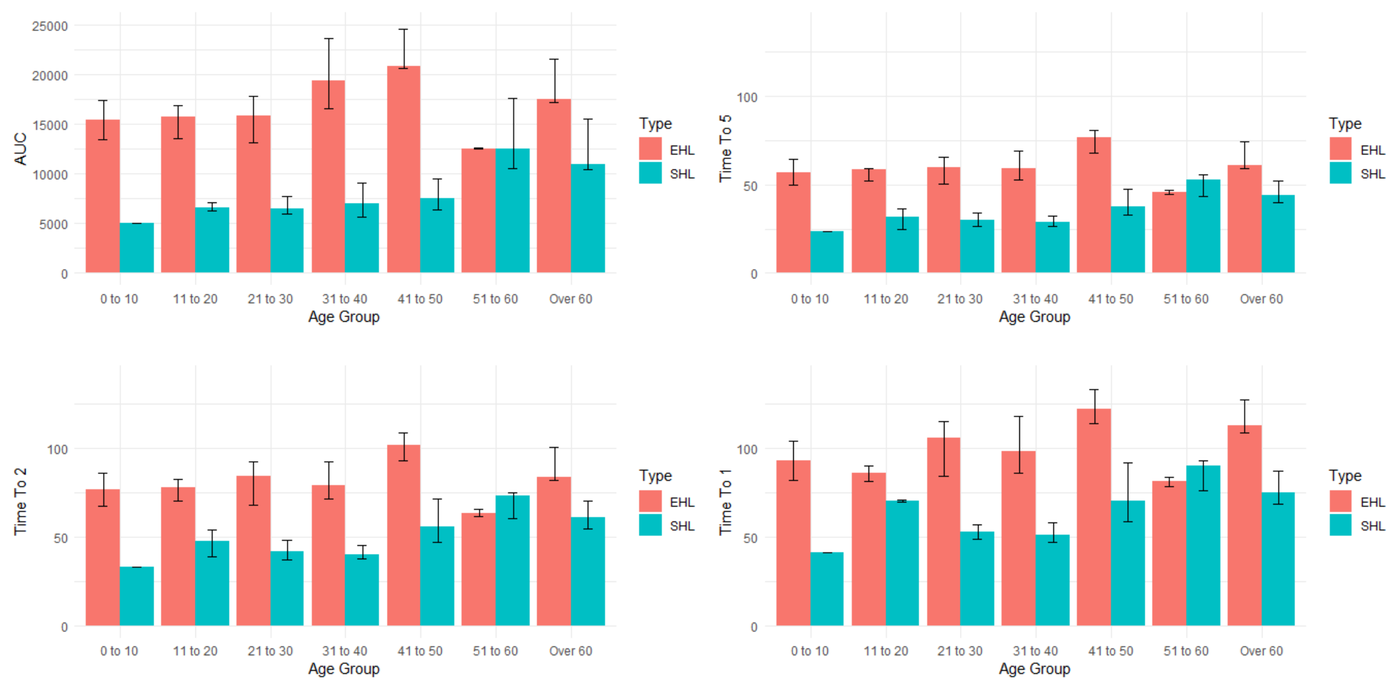


Figure 1. Comparison of pharmacokinetic parameters by age groups and type of medication (EHL or SHL). The graphs show average values and confidence intervals for AUC, time to 5%, time to 2%, and time to 1%. The X-axis corresponds to age groups in years, and the Y-axis to the values of the measured parameters. The colors represent the type of medication: EHL (red) and SHL (blue).

Change History	Number of People
Advate® → Adynovate®	1
Advate® → Immunate® → Adynovate®	1
Advate® → Jivi®	1
Beriate® → Adynovate®	1
HemophilM® → Jivi®	6
Novoeight® → Adynovate®	1
Novoeight® → Jivi®	2
Octanate® → Xyntha® → Adynovate®	1
Xyntha® → Adynovate®	2
Xyntha® → Jivi®	12
Xyntha® → Novoeight® → Jivi®	1

Table 1. Treatment change history and the number of people associated with each medication sequence. This table describes the transitions between different therapies in patients included in the study.

Medication	Number of People with the Medication	Number of Pharmacokinetics
Advate®	3	5
Beriate®	1	1
Immunate®	1	1
Novoeight®	4	5
Xyntha®	16	22
Adynovate®	7	11
Hemophil M®	6	7
Jivi®	22	37
Octanate®	1	3

Table 2. Distribution of medications and pharmacokinetic analysis. The table shows the number of people treated with each medication and the number of pharmacokinetic studies conducted.

CONCLUSIONS

To asses the area under the curve (AUC) and the times to reach specific coagulation factor levels in patients with hemophilia initially treated with SHL coagulation factors and later switched to EHL products.

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REFERENCES

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