CP-079

FACTOR IX INHIBITOR DEVELOPMENT IN CONGENITAL HEMOPHILIA B PATIENTS WITH NONACOG ALFA TREATMENT

P. Pena Villanueva[1], S. Suárez Ordoñez[2], L. Macía Fuentes[3], R. Pampín Sánchez[1], Y. Labeaga Beramendi[1], B. Rodríguez de Castro[1], A. León Barbosa[1], A.I. García Rogada[4], R.M. Núñez Rodríguez-Arango[4], J. Ruíz Salazar[4].

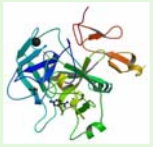
[1]Hospital Universitario de Cabueñes, Pharmacy Department, Gijón, Spain.
[2]Hospital Álvaro Cunqueiro, Hematology and Hemotherapy Department, Vigo, Spain.
[3]Hospital Universitario San Agustín, Pharmacy Department, Avilés, Spain.
[4]Consejería de Sanidad del Principado de Asturias, Pharmacy Department, Oviedo, Spain.

BACKGROUND

The incidence of factor IX inhibitor development in congenital hemophilia B is low (3-5% depending on population) and usually occurs in the first days of treatment. Guidelines suggest that, after 150 days exposed to the drug (ED), testing is only required if clinically indicated. But we detected two cases in which the inhibitors were developed on long term treatments.

PURPOSE

To describe all worldwide reported cases in which the patients develop inhibitors when they were treated with Nonacog alfa. We focus on the time it took to develop the inhibitors, since the treatment started.



METHODS

We searched on VigiBase® and FEDRA® (Global and Spanish Pharmacovigilance Database, respectively), including all spontaneous reports performed in patients with Nonacog alfa who have developed inhibitors in the last 20 years. All patients who didn't have laboratory confirmation were excluded.
Age, gender, reporting country, Nonacog alfa treatment starting date, EDs and confirmation inhibitor testing date were recorded.

RESULTS

52 cases worldwide

45 males, 2 females, 5 unknown

Ages: 9 months – 50 years (19 unknown)

Impossible to confirm EDs in any cases

CHRONOLOGY OF INHIBITOR DEVELOPMENT	
In the first year of treatment	19
* In the first 100 days	12
Between first and second year	2
Between second and third year	1
Between third and fourth year	1
Between fourth and fifth year	2
Between fifth and sixth year	0
Between sixth and seventh year	1
Unknown	26

CONCLUSION

- Patients treated for several years are also susceptible to develop inhibitors.
- It is easy that they have even exceed the 150 EDs.
- Consequently it is so important to monitor all patients, throughout all the treatment.