# FONDAPARINUX IN AN INFANT WITH SUSPECTED HEPARIN-INDUCED THROMBOCYTOPENIA. A CASE REPORT

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## BACKGROUND AND IMPORTANCE:

A **3-month-old infant** (3kg) was admitted in the Paediatric Intensive Care Unit for extracorporeal membrane oxygenation (ECMO) and anticoagulant treatment (AT) was performed with **unfractionated heparin**

During treatment the patient had: A sustained decrease in platelet count (>50% of basal) and inferior cava deep venous thrombosis (DVT)

Once ECMO was finished, AT was modified (**enoxaparin)**

Due to persistent thrombocytopenia and DVT, heparin-induced thrombocytopenia was suspected

→ Anticoagulant was replaced to **fondaparinux** (0.1mg/kg/day)

## AIM AND OBJECTIVES:

To show the need to redose fondaparinux in paediatrics

Registered presentations don't allow fractionation: Single-dose pre-filled syringes based on two concentrations: 5mg/ml and 12.5mg/ml.

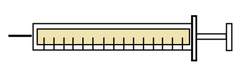
To verify the stability of the preparation through the study of the pharmacotherapeutic effect, indirectly measured by plasma levels of anti-Xa factor (antiXa).

## MATERIAL AND METHODS:

Subcutaneous fondaparinux was started at a dose of 0.3mg/day (0.06mL).

To facilitate administration, the preparation was initially diluted **1mg/mL in normal saline** under sterile conditions.

The dose was packaged in 1ml dead space free syringe with a purged needle.



According to the datasheet, the preparation is stable for 24h at room temperature.

AntiXa was monitored 3 hours after administrations. The dose was adjusted according to **Table1** until the target level (0.5 UI/mL) was reached.

Subsequently, as the dose increase allowed, the undiluted dose (0.4mg/0.08mL) **was fractionated from commercial presentation**. Stability of 7 days in the refrigerator was defined according to the risk matrix (low risk) of the Good Pharmaceutical Practices for the preparation of sterile drugs.

## RESULTS:

The **dose of fondaparinux** was adjusted according to antiXa (**Table2**).

Monitoring of **antiXa**, maintaining correct levels throughout treatment, as shown in **graph**.

Total **platelet count** increased to normal values (after fondaparinux initiation)

Anticoagulation therapy was discontinued after 3 months, upon **confirmation of DVT resolution**.

**TABLE I. Dose Adjustment Fondaparinux**

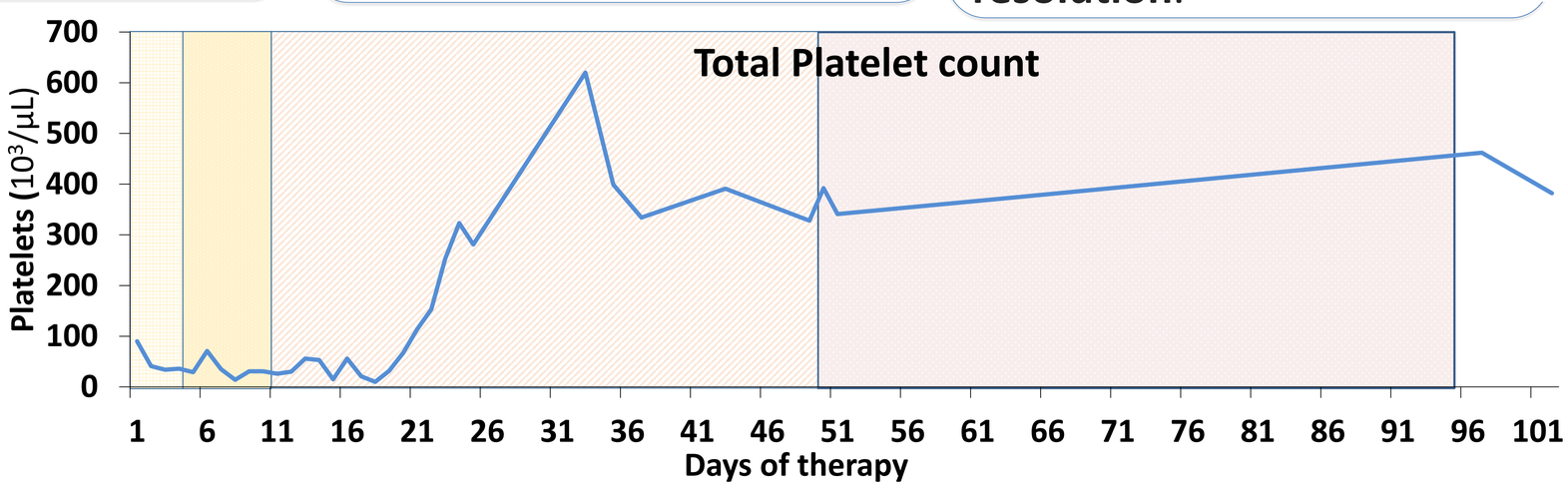
| AntiXa Level (UI/mL) | Dose adjustment |
|---|---|
| < 0,3 | Increase dose by 0,03 mg/kg |
| 0,3 - 0,5 | Increase dose by 0,01 mg/kg |
| **0,5 - 1** | **No change** |
| 1 - 1,2 | Decrease dose by 0,01 mg/kg |
| > 1,2 | Decrease dose by 0,03 mg/kg |

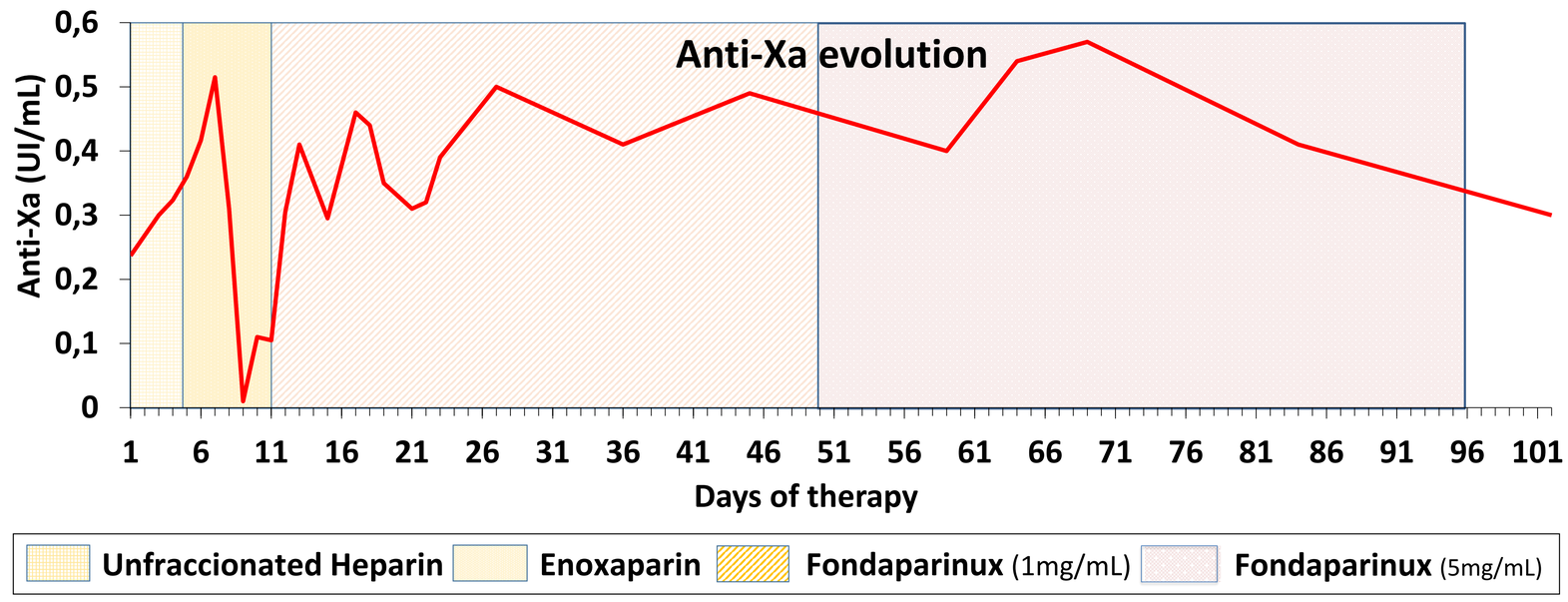
**TABLE II. Dose Adjustment of Fondaparinux in our Patient**

| Day* | Dose (mg) | Fxa (UI/mL)** | Dose adjustment |
|---|---|---|---|
| 1 - 2 | **0,3** | 0,38 | ↑ 0,01 mg/kg |
| 3 - 4 | 0,35 | 0,32 | ↑ 0,01 mg/kg |
| 5 - 8 | 0,38 | 0,44 | ↑ 0,01 mg/kg |
| 9 - 40 | **0,4** | **0,5** | No change |
| 41 | 0,4 | 0,4 | ↑ 0,01 mg/kg |
| 42 - 78 | **0,5** | **0,54** | **No change** |
| 101 | No treatment | 0,30 | |

*Day of treatment with Fondaparinux

**Plasmatic levels 3-h post-administration of Fondaparinux




## CONCLUSION AND RELEVANCE:

Individualized dosing of fondaparinux by dilution or fractionation has allowed DVT treatment, using a commercial presentation unsuitable for pediatrics.

We verify stability of the fractionated dose with the therapeutic effect.