





Comunidad de Madrid

**CPC019** 

# THE USE OF DABIGATRAN ETEXILATE IN HOSPITALISED PATIENTS

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## **BACKGROUND**

Dabigatran etexilate (DE) is a new oral anticoagulant. It was included in the hospital's formulary as a restricted-use drug in December 2009.

### **PURPOSE**

To analyze DE use, compliance with the authorised indications and use restrictions, and to quantify the incidence of adverse events.

#### **METHODS**

An observational, prospective, utilization study was carried out during four months in a general tertiary care hospital.

Pharmacy and Therapeutics Committee approved DE with prescription restricted to the Traumatology and **Geriatrics Departments** 



Primary prevention of thromboembolic events in adults who have undergone elective total hip or knee replacement surgery

Prescription (CPOE program)

Review of patients' treatments, tests and clinical records

**Examination of** indications and posology comparing to the product specifications and the hospital's use protocol

Record the incidence of adverse events related to DE

Standard recommended dose in adults is 220 mg/day during 10 or 28-35 days after total knee or hip replacement respectively



The only difference between the drug specifications and the hospital's protocol is that the latter brings the possibility to < extend the treatment to 4-6 weeks after total knee replacement

#### **RESULTS**

138 patients started treatment with DE

- 78.99% women
- 6.52% had taken it previously
- 97.10% admitted to the Traumatology Dpt.

Licensed indications (89,13%)

"Off-label" (10.87%), mainly after hip fracture

Total hip replacement surgery (26.02%)

Treatment duration stuck to the indications in 82.42%

surgery (73.98%)

the indications in 78,13%

Total knee replacement

Treatment duration stuck to

 Overall, 57.24% of prescriptions stuck to the recommendations.

 Most commonly reported adverse events were: bleeding in surgical wound (7.97%) followed by gastrointestinal side effects (4.35%).

• 15.94% of patients needed red blood cells concentrates transfusion

#### CONCLUSION

Use of dabigatran etexilate was adequate in most patients, but more studies and a close pharmacosurveillance are needed to confirm the safety of this drug in common practice.