Enoxaparin Sodium Biosimilar in the Prophylactic Treatment of Venous Thromboembolism and Thromboembolic Disease: Prophyray Study


BACKGROUND
In Algeria, venous thromboembolism (VTE), whose important clinical manifestations are deep vein thrombosis (DVT) and pulmonary embolism (PE), represents a major public health problem because of its impact on morbidity and mortality and the burden of the disease on the health system [1,2].

Varenox® is the first locally manufactured and approved biosimilar in Algeria. It is an enoxaparin sodium (ES) with established good analytical characterization and manufacturing quality control. The aim of the PROPHYRAY study was to generate real-life data in routine practices and to assess the safety and tolerability of Varenox® in the prophylaxis of VTE.

PATIENTS AND METHODS
This observational, prospective, multicenter study was conducted between April 2021 and May 2022 in 25 different sites in Algeria covering 4 therapeutic areas: ICU, orthopedic surgery, obstetrics and nephrology; (Figure 1).

RESULTS
A total of 550 patients were included and received at least one injection of Varenox®. The mean age was 47 years, women in majority (62.5%). The patients were overweight or obese (class I) for 53% of them, with a history of arterial hypertension (25%), diabetes (7.5%) and renal failure (6.4%). (Figure 2)

Figure 2. Patients’ distribution by BMI class

Reasons for hospitalization were mainly fracture (15.5%), pregnancy (8.3%), COVID-19 (7%) or cancer (7%).

Safety Evaluation
A total of 38 patients (6.9%) experienced at least one AE (C19S=4.9%). Related AEs were reported in 10 patients (1.8%), mainly in nephrology (N=7 arterio-venous fistula). (Table 1).

Table 1. Summary of AE

Table 2. Summary of VTE events

In this study, most patients were treated at prophylactic dose of 0.4ml (80%) or 0.6ml (10%). The average duration of treatment and follow-up were 23 and 24 days, respectively.

DISCUSSION
The efficacy and safety of Low-Molecular-Weight Heparins (LMWH), enoxaparin sodium, have been well documented for the prevention of venous thromboembolism. Biosimilars are clinically and biologically similar to the original (reference) product. They are approved for the same indications and at the same doses. This study highlighted the good safety profile of Varenox® in routine practice, with a very low incidence of related AEs (less than 2%) and a rate of VTE of 1.1%, observed essentially in a heterogeneous population, characterized by the presence of comorbidities and risk factors. No deaths have been reported as being related to treatment.

Conclusion and Perspectives
This study suggests that Varenox® is safe in the prophylaxis of VTE. To our knowledge this is the first large study describing the use of ES in current medical practice in Algeria.

References

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