Introduction

• Treatment for deep vein thrombosis (DVT) traditionally involves initiating therapy with parenteral anticoagulants, followed by transition to a vitamin K antagonist (VKA) such as warfarin or acenocoumarol.

• The need for routine coagulation monitoring and dose adjustment with VKA, plus the potential risk of food and drug interactions, often limits VKA use.

• The link between treatment satisfaction and adherence to DVT treatment has been studied in patients with VKA therapy may impose additional burdens on healthcare systems.

• The oral, direct factor Xa inhibitor rivaroxaban has the potential to improve patient satisfaction, and might be easier to administer without the need for initial heparinization; dosage was a fixed regimen, there is no need for ongoing coagulation monitoring, and food and drug interactions are minimal.

• Objective: to investigate patient-reported treatment satisfaction in the EINSTEIN DVT clinical trial.

Methods

Patients and study design

• In EINSTEIN DVT male and female patients ≥18 years of age with confirmed acute symptomatic proximal DVT without symptomatic pulmonary embolism were randomized to:

  - Rivaroxaban 15 mg twice daily for 3 weeks, followed by 20 mg once daily;

  - Enoxaparin/vitamin K antagonist (VKA) therapy for 6 weeks, followed by VKA therapy.

• The study was designed as a multinational, randomized, double-blind, active-controlled, parallel-group study (data not shown).

• There were differences in ACTS Burdens between subgroups, but the magnitude of the rivaroxaban treatment effect was greater than that for the subgroup effects (data not shown).

ACTS Benefits subscale

• In the rivaroxaban group the patients reported higher satisfaction compared with those in the enoxaparin/VKA group over the total treatment period (least-squares mean 11.73 vs 11.45; p=0.001) (Table 2).

• There was no difference in mean ACTS Benefits score at Day 15, a treatment effect became apparent from Month 2 onwards (Figure 2), the interaction of treatment effect by visit was significant (p=0.019), reflecting inconsistency in patient satisfaction over visits (data not shown).

• The patient subgroup effect on ACTS Benefits showed differences between the groups, the magnitude of the rivaroxaban treatment effect was greater than that for the subgroup effect, with the exception of the country-level effect (data not shown).

Results

Patients and baseline characteristics

• A total of 1472 patients were eligible to participate, patient demographic information and clinical characteristics are shown in Table 1.

• ACTS completion rates at each time point were similar (ACTS Burdens and Benefits subscales ≥95%)

• TSQM completion rates were lower than for ACTS (≥89%), but were similar at each time point.