Science For A Better Life

Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Abstract

Acronym/Title	Real-world comparative effectiveness of rivaroxaban versus heparin and phenprocoumon for the treatment and secondary prevention of venous thromboembolism (RECENT)
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IMPACT study number	21456
Keywords	Venous thromboembolism; rivaroxaban; phenprocoumon; heparin; historical cohort study; effectiveness; safety
Rationale and background	Rivaroxaban, a direct-acting oral anticoagulants (DOAC), is indicated for VTE treatment. No data on the real-world comparative effectiveness of rivaroxaban versus heparin and phenprocoumon is available.
Research question and objectives	The study aimed to assess the risk of recurrent VTE events, fatal bleeding, and end stage renal disease in VTE patients treated with rivaroxaban compared to patients treated sequentially with heparin and phenprocoumon. In addition, differences in healthcare resource consumption and healthcare costs were investigated.
Study design	This was a non-interventional retrospective cohort study, using data between January 2013 and December 2019.
Setting	The source population of this study included all insured members of more than 60 German statutory health insurances (SHIs) contributing data to the InGef database. Patients were followed up from their index date (first anticoagulation dispensing) until the outcome event, discontinuation of the index anticoagulation regimen, death, end of continuous insurance in the SHI or the end of the study period (31 December 2019), whichever came first.
Subjects and study size, including dropouts	Patients had to have a new diagnosis of VTE, and no diagnoses of alternative indications of oral anticoagulant use. The study included a total of 16081 (rivaroxaban) and 6072 (phenprocoumon) patients, which were followed up for at least 12 months.
Variables and data sources	The study was based on German claims data from the InGef (Institute for Applied Healthcare Research Berlin) research database. Main exposure of interest were derived from

	pharmacy dispensations of rivaroxaban, heparin, and phenprocoumon. A large number of pre-defined covariates were extracted to control for potential confounding. Outcomes of interest were hospitalizations for recurrent VTE; fatal bleeding; end stage renal disease; healthcare consumption; and costs.
Results	The risk of recurrent VTE events leading to hospitalization were similar in patients treated with rivaroxaban and phenprocoumon (HR=1.01; 95% CI 0.84-1.21), while the risk of end-stage kidney disease was lower in patients treated with rivaroxaban (HR=0.45; 95% CI 0.30-0.69). The risk of fatal bleeding was not significantly different between treatment groups (HR=1.42; 95% CI 0.74-2.71). Health resource utilization revealed similar service use in both treatment groups. Healthcare costs were also similar in both treatment groups. While patients treated with rivaroxaban had slightly higher overall drug costs per year (cost difference 991.95€; 95% CI 670.31€-1313.59€), the inpatient costs and costs related to kidney diseases were lower than in users of phenprocoumon.
Discussion	Patients treated with rivaroxaban vs. heparin/phenprocumon had similar risks of hospitalization for recurrent VTE or for fatal bleeding, but lower risks of end-stage kidney disease. Health resource utilization and overall healthcare costs were similar in both treatment groups.
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