

Structured benefit–risk assessment for enoxaparin, based on real-world evidence in the context of its label extension, for the extended treatment of deep vein thrombosis and pulmonary embolism, and prevention of its recurrence in patients with active cancer

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February 2, 2023

Abstract

Purpose Guidelines recommend low-molecular-weight heparins (LMWHs) for patients with cancer associated thrombosis. However, until recently, only dalteparin and tinzaparin were approved in the European Economic Area (EEA) for these patients. This study compares the benefit–risk profile of enoxaparin with dalteparin and tinzaparin, based on real-world evidence (RWE) for the extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrence in adult patients with active cancer. **Methods** A semi-quantitative structured benefit–risk assessment was conducted for the label-extension application of enoxaparin employing the following steps of the benefit–risk action team descriptive framework: define decision context; determine key benefit and risk outcomes; identify data sources; extract data; interpret results. **Results** The key benefits were defined as reduced all-cause mortality and VTE recurrence (including symptomatic DVT, fatal PE and non-fatal PE); the key risks were major and non-major bleeding of clinical significance. When compared with other EEA-approved LMWHs (dalteparin, tinzaparin), enoxaparin demonstrated a trend toward favourable effects for the reduction of VTE recurrence and all-cause mortality. There was a trend in favour of other LMWHs for major bleeding, and a trend in favour of enoxaparin for non-major bleeding with no evidence of significant difference between enoxaparin and the comparator groups. **Conclusions** The assessment using RWE demonstrated a favourable benefit–risk profile for enoxaparin similar to that of other EEA-approved LMWHs for the treatment of DVT and PE and the prevention of recurrence in patients with active cancer and thus supported the label-extension approval.

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