Biosimilar Enoxaparin for the Prevention or Treatment of Thrombosis and Cardiovascular Conditions

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Questions or requests for information about this report can be directed to requests@cadth.ca
Key Messages

• Three randomized controlled trials and 1 non-randomized study were identified regarding the comparative clinical effectiveness of biosimilar versus reference enoxaparin in the prevention or treatment of thrombosis and cardiovascular conditions for adult or pediatric patients.
• No relevant literature was identified regarding the clinical effectiveness of switching from reference to biosimilar enoxaparin in the prevention or treatment of thrombosis and cardiovascular conditions for adult or pediatric patients.

Research Questions

1. What is the clinical effectiveness for adult or pediatric patients of switching from reference to biosimilar enoxaparin in the prevention or treatment of thrombosis and cardiovascular conditions?
2. What is the comparative clinical effectiveness for adult or pediatric patients of biosimilar versus reference enoxaparin for in prevention or treatment of thrombosis and cardiovascular conditions?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were enoxaparin and biosimilar pharmaceuticals. No filters were applied to limit the retrieval by study type. Comments, newspaper articles, editorials, conference abstracts, and letters were excluded. Where possible, retrieval was limited to the human population. The search was also limited to English-language documents published between January 1, 2011 and August 10, 2021. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.
Results

Four relevant references were identified for this report. Three randomized controlled trials and 1 non-randomized study were identified regarding the comparative clinical effectiveness of biosimilar versus reference enoxaparin for adult or pediatric patients in the prevention or treatment of thrombosis and cardiovascular conditions. No relevant health technology assessments or systematic reviews were identified regarding the comparative clinical effectiveness of biosimilar versus reference enoxaparin for adult or pediatric patients in the prevention or treatment of thrombosis and cardiovascular conditions. No relevant literature was identified regarding the clinical effectiveness for adult or pediatric patients of switching from reference to biosimilar enoxaparin in the prevention or treatment of thrombosis and cardiovascular conditions.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

Overall Summary of Findings

Three randomized controlled trials and 1 non-randomized study were identified regarding the comparative clinical effectiveness of biosimilar versus reference enoxaparin for adult or pediatric patients in the prevention or treatment of thrombosis and cardiovascular conditions. All 3 randomized controlled trials compared a biosimilar enoxaparin to the branded Sanofi enoxaparin and concluded that the investigated biosimilars exhibited comparative safety and clinical effectiveness to the Sanofi enoxaparin. The first randomized controlled trial

Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>Population</td>
<td>Patients (any age), with or without cancer, for any of the following indications:</td>
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<tr>
<td></td>
<td>• Prophylaxis of DVT in patients undergoing surgery</td>
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<td></td>
<td>• Prophylaxis of DVT in non-surgical patients who are at risk of DVT</td>
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<td>• Prevention of thrombus formation in the extra-corporeal circulation during hemodialysis</td>
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<td></td>
<td>• Treatment of unstable angina or non-Q wave myocardial infarction</td>
</tr>
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<td></td>
<td>• Treatment of ST-elevation myocardial infarction</td>
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<tr>
<td>Intervention</td>
<td>Q1: Switching from reference enoxaparin (i.e., Lovenox, Clexane) to biosimilar enoxaparin (e.g., Inclunox, Noromby, Redesca, Inhixa, Heparinox, generic enoxaparin)</td>
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<td></td>
<td>Q2: Biosimilar enoxaparin (e.g., Inclunox, Noromby, Redesca, Inhixa, Heparinox, generic enoxaparin)</td>
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<tr>
<td>Comparator</td>
<td>Q1: Continuous use of reference enoxaparin (i.e., Lovenox, Clexane); pre- and post-switch comparisons</td>
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<tr>
<td></td>
<td>Q2: Reference enoxaparin (i.e., Lovenox, Clexane)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Clinical effectiveness (e.g., clinical response, health-related quality of life, mortality) and safety (e.g., adverse events, withdrawal due to adverse event)</td>
</tr>
<tr>
<td>Study designs</td>
<td>HTAs, systematic reviews, RCTs, non-randomized studies</td>
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DVT = deep vein thrombosis; HTA = health technology assessment; Q = question; RCT = randomized controlled trial.
evaluated the comparative efficacy and safety of biosimilar Cristalia versus the branded Sanofi enoxaparin in patients undergoing major abdominal surgery at risk for venous thromboembolism (VTE). The second randomized controlled trial evaluated the branded Sanofi enoxaparin and compared it to the biosimilar Heptron in patients diagnosed with lower-extremity deep vein thrombosis and requiring VTE. The third randomized controlled trial compared generic eurofarma-enoxaparin to Sanofi enoxaparin as a prophylaxis for VTE in patients who underwent major abdominal surgery. The non-randomized retrospective study investigated the comparative effectiveness of the biosimilar Inhixa to the reference enoxaparin Clexane in preventing VTE in medically ill patients undergoing major abdominal surgery. The authors concluded that the biosimilar Inhixa is an appropriate alternative to the branded Clexane through comparing the number of bleeding and thrombotic events in the 2 cohorts. Overall, all 4 identified studies concluded that the biosimilar enoxaparin has comparable effectiveness to reference enoxaparin in the investigated population groups.

No relevant literature was identified regarding the clinical effectiveness of switching from reference to biosimilar enoxaparin; therefore, no summary can be provided. Additionally, no relevant literature was found for either of the identified research questions evaluating patients with cancer; therefore, no summary can be provided.
References

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials

Non-Randomized Studies
Appendix 1: References of Potential Interest

Previous CADTH Reports


Health Technology Assessments

Product Assessment Report

Systematic Reviews and Meta-Analyses

Alternative Outcomes

Randomized Controlled Trials

Alternative Population


Review Articles


Additional References


