Switching From Reference to Biosimilar Insulin Lispro for Patients with Diabetes Mellitus (Type 1 or 2)

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Key Message

• One randomized controlled trial was identified regarding the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2).

Research Question

What is the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2)?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the international HTA database, 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 concept was insulin lispro biosimilars. No filters were applied to limit the retrieval by study type. Conference abstracts were excluded from the search results. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2016 and February 9, 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

One randomized controlled trial was identified regarding the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2). No relevant health technology assessments, systematic reviews, or non-randomized studies were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.
**Table 1: Selection Criteria**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tr>
<td><strong>Population</strong></td>
<td>Patients (any age) with diabetes mellitus (type 1 or 2)</td>
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<tr>
<td><strong>Intervention</strong></td>
<td>Switching from reference insulin lispro (i.e., Humalog) to biosimilar insulin lispro (i.e., Admelog)</td>
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<tr>
<td><strong>Comparator</strong></td>
<td>Continuous use of reference insulin lispro; pre/post switch comparisons</td>
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<td><strong>Outcomes</strong></td>
<td>Effectiveness (e.g., change in disease severity, disease complications, health-related quality of life) and safety (e.g., adverse events, withdrawal due to adverse event)</td>
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<tr>
<td><strong>Study designs</strong></td>
<td>Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies</td>
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**Overall Summary of Findings**

One crossover randomized controlled trial\(^1\) assessed the safety of switching between reference insulin lispro and biosimilar insulin lispro administered by continuous subcutaneous insulin infusion pumps for patients with type 1 diabetes mellitus. Patients were randomized to receive the reference or biosimilar for 4 weeks, then switched to the other treatment for 4 weeks.\(^1\) The number of patients reporting at least 1 infusion set occlusion (ISO) was low in both treatment groups, and the estimated difference in ISO risk was not significantly different between groups.\(^1\) The event rate of hypoglycemia and the percentage of patients who experienced any treatment-emergent adverse events were also similar between treatment groups.\(^1\)

**References**

**Health Technology Assessments**
No literature identified.

**Systematic Reviews and Meta-analyses**
No literature identified.

**Randomized Controlled Trials**

*Crossover Study Assessing Insulin Lispro Administered by Continuous Subcutaneous Insulin Infusion Pump*


**Non-Randomized Studies**
No literature identified.
Appendix 1: References of Potential Interest

Systematic Reviews and Meta-analyses

**Alternative Intervention — Not Specific to Insulin Lispro and Not Switching**


Randomized Controlled Trials

**Alternative Intervention — Not Switching**


**Alternative Outcomes — Pharmacokinetics and Pharmacodynamics**


Review Articles

**Alternative Intervention — Not Switching**


**Alternative Intervention — Not Specific to Insulin Lispro and Not Switching**