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CADTH Reference List

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

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Summary of Abstracts

CADTH

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Key Message

- Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference to biosimilar insulin aspart in adult or pediatric patients with diabetes mellitus (Type 1 or Type 2).

Research Question

What is the clinical effectiveness of switching from reference to biosimilar insulin aspart in adult or pediatric patients with diabetes mellitus (Type 1 or Type 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 concepts were reference insulin aspart and biosimilars. No search filters were applied to limit retrieval by study type. Conference abstracts were excluded. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2016 and November 1, 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

Two randomized controlled trials[1,2] were identified regarding the clinical effectiveness of switching from reference to biosimilar insulin aspart in adult or pediatric patients with diabetes mellitus (Type 1 or Type 2). No 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

Criteria	Description
Population	Patients (any age) with diabetes mellitus (Type 1 or 2)
Intervention	Switching from reference insulin aspart (i.e., NovoRapid) to biosimilar insulin aspart (i.e., Trurapi)
Comparator	Continuous use of reference insulin aspart; pre/post switch comparisons
Outcomes	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)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies

Overall Summary of Findings

Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference to biosimilar insulin aspart in adult or pediatric patients with diabetes mellitus (Type 1 or Type 2).[1,2] One open-label randomized controlled trial (i.e., GEMELLI 1 study) transitioned adult participants with diabetes (Type 1 or Type 2) from Novolog/NovoRapid insulin aspart (NN-Asp) or Humalog R/Liprolog R to either NN-Asp or biosimilar insulin aspart SAR341402 (SAR-Asp).[1] In a subgroup analysis of the GEMELLI 1 trial, no differences in hemoglobin A1C change, changes in insulin doses, hypoglycemia, and safety outcomes were found between those transitioned to SAR-Asp and NN-Asp at 26 and 52 weeks within the subgroup of patients originally receiving NN-Asp.[1] An open-label crossover trial randomized adult patients with type 1 diabetes to a self-administered treatment sequence of SAR-Asp to NN-Asp or SAR-Asp NN-Asp through an insulin pump.[2] Both treatments were well tolerated by patients, with no significant difference in infusion set occlusions over a 4-week treatment period.[2] Additionally, no differences in hypoglycemia, adverse events, hypersensitivity, and injection site reactions were detected between treatments.[2]

References

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

1. Shah VN, Franek E, Wernicke-Panten K, Pierre S, Mukherjee B, Sadeharju K. Efficacy, safety, and immunogenicity of insulin aspart biosimilar SAR341402 compared with originator insulin aspart in adults with diabetes (GEMELLI 1): a subgroup analysis by prior type of mealtime insulin diabetes therapy research, treatment and education of diabetes and related disorders. *Diabetes Ther.* Feb 2021; 12(2): 557-568. PubMed

2. Thrasher J, Polsky S, Hovsepian L, et al. Safety and tolerability of insulin aspart biosimilar SAR341402 versus originator insulin aspart (NovoLog) when used in insulin pumps in adults with Type 1 diabetes: a randomized, open-label clinical trial. *Diabetes Technol Ther.* 09 2020; 22(9): 666-673. PubMed

Non-Randomized Studies

No literature identified.

Appendix 1: References of Potential Interest

Randomized Controlled Trials

Alternative Comparator – Not Switching

3. Karonova TL, Mayorov AY, Magruk MA, et al. Safety and efficacy of GP40071 compared with originator insulin aspart (NovoRapid R Penfill R) in Type 1 diabetes mellitus. *J Comp Eff Res*. 06 2021; 10(9): 763-775. PubMed

4. Garg SK, Wernicke-Panten K, Wardecki M, et al. Efficacy and safety of insulin aspart biosimilar SAR341402 versus originator insulin aspart in people with diabetes treated for 26 weeks with multiple daily injections in combination with insulin glargine: a randomized open-label trial (GEMELLI 1). *Diabetes Technol Ther*. 02 2020; 22(2): 85-95. PubMed

Intervention Not Specific to NovoRapid

5. Garg SK, Wernicke-Panten K, Wardecki M, et al. Safety, immunogenicity, and glycemic control of insulin aspart biosimilar SAR341402 versus originator insulin aspart in people with diabetes also using insulin glargine: 12-month results from the GEMELLI 1 trial. *Diabetes Technol Ther*. 07 2020; 22(7): 516-526. PubMed