Teduglutide for treating short-bowel syndrome in adults: a meta-analysis of real-world evidence compared to clinical trial data

Background

Teduglutide (Ilenium™) is a glucagon-like peptide-2 analogue that has been shown to reduce weekly parenteral nutrition (PN) volume and improve intestinal absorption in patients with Short Bowel Syndrome (SBS). However, real-world evidence is needed to determine whether the clinical trial findings are relevant to real-world patients, and what impact this will have on healthcare costs.

Methods

Systematic review:

- Real-world data (systematic review to identify non-interventional studies of Teduglutide or placebo with ≥ 80% of baseline PN use) was included. Conducted searches up to May 2021, for 6 and 12 months.
- Studies were included if they provided complete real-world data and clinical information.

Data extraction:

- Data were extracted from 9 studies. Teduglutide was compared to placebo in 7 trials and to another treatment in 2 trials.
- Data on mean remaining small bowel length, time to clinical independence, self-report of clinical independence, and patient-reported outcomes were collected.

Meta-analysis:

- Meta-analysis of real-world data was conducted using a random-effects model if heterogeneity was ≥ 50% or fixed-effect model if heterogeneity was < 50%.
- Two outcomes were of interest:
  - Clinical response: proportion of patients achieving ≥ 20% reduction in weekly PN volume
  - Clinical independence: proportion of patients achieving 100% reduction in weekly PN volume

Statistical testing:

- Sensitivity analyses were performed to determine whether the results were robust to different statistical models.

Results:

The systematic literature review identified 8 studies for inclusion in the meta-analysis.

Collated raw data

- The STEPS clinical trial showed that over 6 months, Teduglutide was more efficacious than placebo in allowing patients to reduce their dependence on PN (p < 0.001).
- Individual real-world studies of Teduglutide have reported a ≥20% and a 100% reduction in weekly PN volume in 60% and 50% of patients, respectively.
- For the purpose of health technology assessment (HTA), it is important to understand the clinical and cost-effectiveness results from real-world data, as well as the clinical trial data for the treatment of SBS-IF with Teduglutide.

Discussion

- The primary objective of this study was to determine whether clinical trial findings are relevant to real-world patients, and what impact this will have on healthcare costs.
- The results suggest that Teduglutide is effective in reducing PN volume and improving clinical independence in both clinical trials and real-world settings.
- In conclusion, Teduglutide is a promising treatment option for SBS-IF patients, with evidence demonstrating improved clinical and cost-effectiveness outcomes in real-world settings.

References:

- Lam 2018
- Martin 2021
- Tamara 2020
- Schoeler 2018
- Puello 2020
- Joly 2020
- Ukleja 2018
- Pevny 2019
- Fix ed effect model
- Random effects model

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