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# Scientific evidence of teduglutide in parenteral support in patients with short bowel syndrome: a systematic review

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## Abstract

**Introduction:** Short bowel syndrome (SBS) is a heterogeneous condition in which patients suffer from impaired intestinal absorption due to absolute loss of the intestine. Approximately 75% of SBS cases develop after a single massive bowel resection. Patients with SBS with intestinal failure (II) [SBS-II] experience decreased quality of life and increased morbidity and mortality due to their dependence on parenteral support (PS). Teduglutide is a degradation-resistant peptide 2 (GLP-2) analog that increases the functional and structural capacity of the intestine. **Objective:** To analyze the scientific evidence for teduglutide in parenteral support in patients with short bowel syndrome. **Methods:** The systematic review rules of the PRISMA Platform were followed. The search was conducted from June to August 2024 in the Web of Science, Scopus, PubMed, Science Direct, Scielo, and Google Scholar databases. The quality of the studies was based on the GRADE instrument and the risk of bias was analyzed according to the Cochrane instrument. **Results and Conclusion:** A total of 91 articles were found. 29 articles were fully evaluated and 07 were included and developed in the present systematic review study. Considering the Cochrane tool for risk of bias, the overall assessment resulted in 20 studies with a high risk of bias and 22 studies that did not meet GRADE and AMSTAR-2. Most studies showed homogeneity in their results, with $X^2$=82.7%>50%. It was concluded that teduglutide can restore intestinal structural and functional integrity, promote mucosal growth, reduce gastric emptying and secretion, and increase nutrient absorption and enteral independence from parenteral nutrition. The 24-week treatment time with teduglutide was generally well tolerated in patients with short bowel syndrome with intestinal failure. The clinical studies showed that teduglutide treatment reduced the volumes and number of days of parenteral support for patients with short bowel syndrome with intestinal failure.

**Keywords:** Short bowel syndrome. Parenteral nutrition. Teduglutide.

## Introduction

Short bowel syndrome (SBS) is a heterogeneous condition in which patients suffer from impaired intestinal absorption due to absolute loss of bowel as a result of surgical resection or disease-associated bowel destruction. Approximately 75% of SBS cases develop after a single massive bowel resection; whereas the remaining 25% occur after multiple resections. Approximately two-thirds of patients who develop SBS survive the initial hospitalization, and a similar number survive the first year after developing SBS. Age and underlying disease primarily determine the long-term outcome of the patient **[1,2]**.

Furthermore, patients with SBS with intestinal failure (II) **[SBS-II]** denote a decreased quality of life (QOL) and increased morbidity and mortality due to their dependence on parenteral support (PS), consisting of parenteral nutrition (PN) and/or fluid and micronutrient support. Despite a fairly precise definition of the disease, the true prevalence and incidence of SBS in adults are difficult to determine, as there is a lack of consistently applied disease criteria, the absence of reliable databases, and the fact that estimates vary greatly by region and refer mainly to patients receiving long-term PS. However, most studies classify SBS-II as a rare disease with prevalence rates well below the internationally accepted threshold of 20 per 1,000,000 population **[1,3,4]**.

In this sense, the interindividual heterogeneity of the clinical presentation and the variable extent of PS dependence can be explained by the nutritional-metabolic deficit caused by differences in the remaining anatomy of the intestine. Almost half of the patients remain dependent on PS **[4-9]**.

Teduglutide is a degradation-resistant peptide-2 (GLP-2) analog, increasing the functional and structural capacity of the intestine **[1]**. Clinical studies have demonstrated that patients with SBS-II who were treated with teduglutide were able to reduce and even discontinue PS with varying degrees of success. However, teduglutide is expensive, with an estimated cost of over €237,680 per patient per year, and it is necessary to assess the socioeconomic impact associated with treating patients with SBS-II with teduglutide **[10-12]**.

The goal of medical and surgical treatment for patients with SBS-II is to maximize the absorptive capacity of the intestinal remnant so that the need for PS can eventually be reduced or eliminated. Given this, daily subcutaneous administration of teduglutide is clinically effective in reducing dependence on PS and potentially improving the health-related quality of life of patients with SBS-II **[13]**.

Given this, the present study aimed to analyze the scientific evidence of teduglutide in parenteral support in patients with short bowel syndrome.

## Methods

### Study Design

This study followed the international systematic review model, following the PRISMA (preferred reporting items for systematic reviews and meta-analysis) rules. Available at: http://www.prisma-statement.org/?AspxAutoDetectCookieSupport=1. Accessed on: 07/20/2024. The AMSTAR-2 (Assessing the methodological quality of systematic reviews) methodological quality standards were also followed. Available at: https://amstar.ca/. Accessed on: 07/20/2024.

### Data Sources and Search Strategy

The literature search process was carried out from June to August 2024 and developed based on Web of Science, Scopus, Embase, PubMed, Lilacs, Ebsco, Scielo, and Google Scholar, covering scientific articles from various periods to the present day. The following descriptors (MeSH Terms) were used: "Short bowel syndrome. Parenteral nutrition. Teduglutide", and using the Boolean "and" between the MeSH terms and "or" between the historical findings.

### Study Quality and Risk of Bias

The quality was classified as high, moderate, low, or very low regarding the risk of bias, clarity of comparisons, precision, and consistency of analyses. The most evident emphasis was on systematic review articles or meta-analyses of randomized clinical trials, followed by randomized clinical trials. Low quality of evidence was attributed to case reports, editorials, and brief communications, according to the GRADE instrument. The risk of bias was analyzed according to the Cochrane instrument by analyzing the Funnel Plot graph (Sample size versus Effect size), using Cohen's d test.

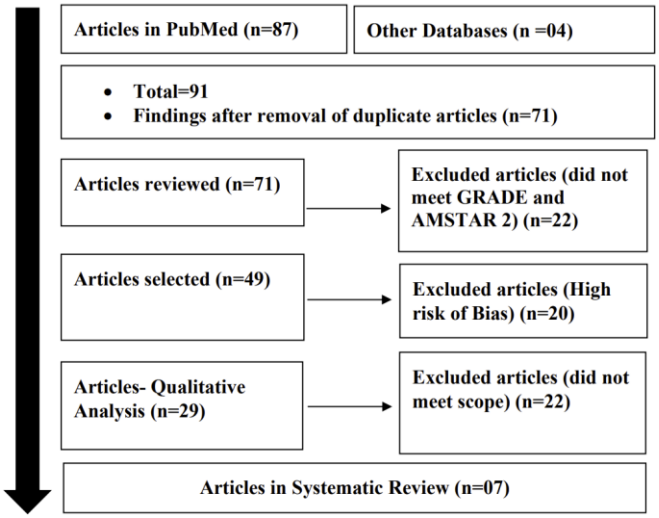
## Results and Discussion

### Summary of Findings

A total of 91 articles were found that were submitted to eligibility analysis, and 7 final studies were selected to compose the results of this systematic review. The studies listed were of medium to high quality (Figure 1), considering the level of scientific evidence of studies such as meta-analysis, consensus, randomized clinical, prospective, and observational. Biases did not compromise the scientific basis of the studies. According to the GRADE instrument, most

studies presented homogeneity in their results, with $X^2$=82.7%>50%. Considering the Cochrane tool for risk of bias, the overall assessment resulted in 20 studies with a high risk of bias and 22 studies that did not meet GRADE and AMSTAR-2.

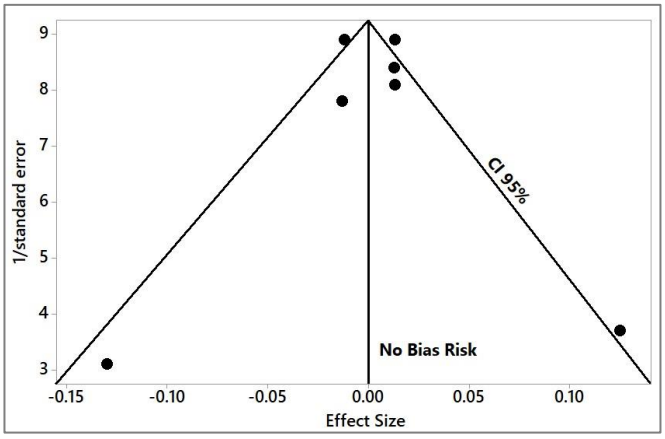
Figure 1. Selection of articles by exclusion based on GRADE and AMSTAR-2.




Source: Own authorship.

Figure 2 presents the results of the risk of bias of the studies using the Funnel Plot, showing the calculation of the Effect Size (Magnitude of the difference) using Cohen's Test (d). Precision (sample size) was determined indirectly by the inverse of the standard error (1/Standard Error). This graph had a symmetrical behavior, not suggesting a significant risk of bias, both among studies with small sample sizes (lower precision) that are shown at the bottom of the graph and in studies with large sample sizes that are shown at the top.

Figure 2. The symmetrical funnel plot does not suggest a risk of bias among the studies with small sample sizes that are shown at the bottom of the graph. Studies with high confidence and high recommendation are shown above the graph (n=07 studies).




Source: Own authorship.

## Main Clinical Findings

According to the literature findings, it has been shown that teduglutide can restore intestinal structural and functional integrity by promoting mucosal growth and reducing gastric emptying and secretion, as it increases villus height and crypt depth in the small intestine mucosa, promoting nutrient absorption and enteral independence from parenteral nutrition (PN). These factors can increase fluid and nutrient absorption in patients with short bowel syndrome with bowel failure (SBS-II). In this sense, a prospective study analyzed whether teduglutide reduces parenteral support (PS) in patients with SBS-II. A 24-week study was conducted in patients with SBS-II who received subcutaneous teduglutide (0.05 mg/kg/d; n=43) or placebo (n=43) once daily. There were significantly better results in the teduglutide group (63%) than in the placebo group (30%). At week 24, the mean reduction in SP volume in the teduglutide group was 4.4±3.8 L/week (baseline 12.9±7.8 L/week) compared with 2.3±2.7 L/week (baseline 13.2±7.4 L/week) in the placebo group. Teduglutide increased plasma concentrations of citrulline, a biomarker of intestinal mucosal mass. Treatment-related adverse events leading to study discontinuation were similar between patients receiving teduglutide (n=2) and placebo (n=3) **[14]**.

Authors Lam et al. (2018) **[15]** performed a retrospective analysis of patients managed in a bowel rehabilitation program to identify patients (n=18) with SBS-II treated with teduglutide. A total of 11 patients (61%) achieved full enteral independence from PS and/or intravenous (IV) fluids within a median time of 10 months. The volume requirement for parenteral nutrition was reduced in most patients. Ten of the 11 patients (91%) who achieved enteral autonomy had a colon. The presence of a colon appears to be favorable in achieving enteral independence from parenteral nutrition, regardless of residual small bowel length.

A retrospective study by the authors Siu et al. (2024) **[16]** investigated the clinical outcomes of patients with SBS, chronic intestinal failure, and Crohn's disease treated with teduglutide. The primary outcome measured was a reduction in PS by ≥20% of volume, with PS defined as the use of parenteral nutrition (PN) or intravenous fluids (IVF). Thirty-two patients with SBS, chronic intestinal failure, and Crohn's disease received teduglutide. Comparing clinical outcomes before and after teduglutide, 26 of 32 patients achieved the primary outcome of ≥20% reduction in PS. A reduction was observed in patients requiring PN + IVF, with corresponding increases in patients requiring PN alone and IVF alone. Across all 3 groups, a total of 23 patients received PN before teduglutide, which decreased to 14 after teduglutide. Weekly PN volume reduced from 7.00

to 3.55 L and weekly frequency decreased from 7.00 to 3.00 instances. Reductions in weekly volume and frequency were observed among all patients receiving IVF support (25 vs 15). Secondary outcomes included improvements in patient-reported subjective symptoms (84.4%), stool output (90.6%), patients meeting criteria for diarrhea/high ostomy output (27 vs 14), and use of exclusive antidiarrheal medications (3.0 vs 2.0). Despite this, the long-term safety of teduglutide remains a concern, particularly regarding its potential for the development of hyperamylasemia and hyperlipasemia. Thus, a retrospective study by Kim et al. (2024) **[17]** evaluated outcomes and adverse events, focusing on hyperamylasemia and hyperlipasemia, through chart review. Thirteen eligible patients were identified who used teduglutide. Of these, the majority (84.6%) had reduced parenteral support. A high incidence (72.7%) of nonpathological pancreatic enzyme elevation was observed in patients treated with teduglutide.

Additionally, the multinational Short Bowel Syndrome Registry study (NCT01990040) evaluated the long-term safety of teduglutide in patients with SBS-II in clinical practice. A total of 1411 adult patients (679 treatment-experienced; 732 treatment-naïve) were enrolled at 124 sites in 17 countries. The mean (standard deviation) age at enrollment was 55.4 (15.46) years, and 60.2% of patients were women. Crohn's disease was the most common cause of major bowel resection in both treatment-experienced (34.1%) and treatment-naïve (20.4%) patients. A similar proportion of treatment-experienced and treatment-naïve patients had a prior history of colorectal polyps (2.7% vs. 3.6%), while proportionally fewer treatment-experienced patients reported a history of colorectal cancer (1.8% vs. 6.2%) or any malignancy (17.7% vs. 30.0%) than treatment-naïve patients. Treatment-naïve patients received a numerically greater mean volume of parenteral nutrition and/or intravenous fluids than treatment-experienced patients (12.4 **[8.02]** vs. 10.1 **[6.64]** L/week). Treatment-experienced patients received a mean teduglutide dosage of 0.05 mg/kg/day. Overall, treatment-experienced and treatment-naïve patients had similar baseline characteristics **[18]**.

Also, patients with SBS who are dependent on home parenteral nutrition (HPN) commonly cycle infusions during the night, likely contributing to circadian misalignment and sleep disruption. A single-arm, controlled, quasi-experimental pilot study was to examine the feasibility, safety, and efficacy of daytime HPN infusions in adults with SBS without diabetes. A total of 20 patients (mean age, 51.7 years; 75% women; mean body mass index, 21.5 kg/m$^2$) completed the study. Nighttime infusions began at 9:00 PM and daytime infusions at 9:00 AM. No serious adverse events were observed. There were no differences in 24-hour blood glucose (daytime median, 93.00 mg/dL; 95% CI, 87.7-99.9 mg/dL, compared with nighttime median, 91.1 mg/dL; 95% CI, 89.6-99.0 mg/dL). During the day (09:00–21:00), mean glucose concentrations were 13.5 (5.7–22.0) mg/dL higher, and time spent <70 mg/dL was 15.0 (−170.0, 22.5) min shorter with daytime HPN than with nighttime HPN. Conversely, during the day (21:00–09:00), glucose concentrations were 16.6 (−23.1, −2.2) mg/dL lower with daytime HPN than with nighttime HPN. Therefore, daytime HPN was feasible and safe in adults with SBS and, compared with nighttime HPN, improved subjective sleep without increasing 24-hour glucose concentrations **[19]**.

Finally, a recent (2024) meta-analysis study summarized the evidence on the efficacy and safety of exogenous GLP-2 in patients with SBS. Twenty-three clinical trials with 843 patients were included. Patient ages ranged from 4.0 to 62.4 years. Treatment doses were 0.1, 0.05, and 0.025 mg/kg/day for teduglutide; 5 and 10 mg/week for apraglutide; and 0.1, 1, and 10 mg/day for glepaglutide. Treatment duration ranged from 1 to 32 weeks. Regarding citrulline level, 0.1 mg/kg/day teduglutide had the largest mean difference (MD; 14.77; 95% CI, 10.20-19.33), followed by 0.05 mg/kg/day (13.04; 95% CI, 9.79-16.2) and 0.025 mg/kg/day (7.84; 95% CI, 2.42-13.26) teduglutide. Furthermore, the effect estimate showed significant differences between all teduglutide dose groups and the control group. Different doses of glepaglutide were analyzed to assess the effect on alkaline phosphatase (ALP) levels, where 0.1 mg/day glepaglutide showed a significantly higher MD (20.71; 95% CI, 2.62-38.80) than 1 mg/day (the reference) and 10 mg/day (8.45; 95% CI, -10.72 to 27.62) glepaglutide. However, 0.1 vs 10 mg glepaglutide has an MD of -14.57 (95% CI, -437.24 to 148.11) for the indirect estimate, whereas 10 mg glepaglutide has an MD of 8.45 (95% CI, -10.72 to 27.62) for the network estimate. Regarding safety outcomes, there was no significant difference between all teduglutide and apraglutide dose groups compared with the control group **[20]**.

## Conclusion

It was concluded that teduglutide can restore intestinal structural and functional integrity, promoting mucosal growth and reducing gastric emptying and secretion, increasing nutrient absorption and enteral independence from parenteral nutrition. The 24-week treatment period with teduglutide was generally well tolerated in patients with short bowel syndrome with intestinal failure. The clinical studies analyzed showed that treatment with teduglutide reduced the volumes

and number of days of parenteral support for patients with short bowel syndrome with intestinal failure.

## CRediT

Author contributions **Conceptualization**- Lucila Maria de Almeida Lopes, Karlla Gabrielly Claudino Santos, Vittor Cândido Soares, Sarah Rachel Pereira de Moura Lima; **Data curation-** Lucila Maria de Almeida Lopes, Karlla Gabrielly Claudino Santos, Vittor Cândido Soares, Ricardo de Oliveira Carvalho, Simone Drbal de Oliveira, Divina Seila de Oliveira, Jeffeson Alexandre Azevedo de Araujo, Sarah Bernardon de Oliveira, Hugo Menezes Lopes; **Formal Analysis-** Lucila Maria de Almeida Lopes, Sarah Rachel Pereira de Moura Lima, Ricardo de Oliveira Carvalho, Simone Drbal de Oliveira, Divina Seila de Oliveira, Hugo Menezes Lopes; **Investigation-** Lucila Maria de Almeida Lopes, Vittor Cândido Soares, Jeffeson Alexandre Azevedo de Araujo, Sarah Bernardon de Oliveira, Hugo Menezes Lopes; **Methodology-** Lucila Maria de Almeida Lopes, Sarah Rachel Pereira de Moura Lima; **Project administration-** Lucila Maria de Almeida Lopes; **Supervision: -** Lucila Maria de Almeida Lopes; **Writing - original draft-** Lucila Maria de Almeida Lopes, Karlla Gabrielly Claudino Santos; Vittor Cândido Soares, Sarah Rachel Pereira de Moura Lima, Ricardo de Oliveira Carvalho, Simone Drbal de Oliveira, Divina Seila de Oliveira, Jeffeson Alexandre Azevedo de Araujo, Sarah Bernardon de Oliveira, Hugo Menezes Lopes; **Writing-review & editing-** Lucila Maria de Almeida Lopes, Karlla Gabrielly Claudino Santos; Vittor Cândido Soares, Sarah Rachel Pereira de Moura Lima, Ricardo de Oliveira Carvalho, Simone Drbal de Oliveira, Divina Seila de Oliveira, Jeffeson Alexandre Azevedo de Araujo, Sarah Bernardon de Oliveira, Hugo Menezes Lopes.

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Not applicable.

## Informed Consent

It was applicable.

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No additional data are available.

## Conflict of Interest

The authors declare no conflict of interest.

## Similarity Check

It was applied by Ithenticate®.

## Application of Artificial Intelligence (AI)

Not applicable.

## Peer Review Process

It was performed.



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