46th ESPEN Congress
on Clinical Nutrition & Metabolism
Milan, Italy • 7-10 September 2024
CLINICAL NUTRITION : *"THE"* TRANSVERSAL SCIENCE

Longer-term effectiveness and safety of teduglutide in adults with short bowel syndrome in Canada using real-world evidence

J. P. Allard[1], D. C. Daoud[2], M. Raman[3], J. Jin[4], L. Gramlich[4], M. M. L. Nguyen[5], J. Weiss[5], J. H. Chen[6], L. Demchyshyn[6]

1. Toronto General Hospital, University Health Network, Toronto, ON; 2. Department of Medicine, Division of Gastroenterology, Centre Hospitalier de l'Université de Montréal (CHUM), University of Montreal, Montreal, Quebec; 3. Division of Gastroenterology, University of Calgary, Calgary, AB; 4. Division of Gastroenterology, Department of Medicine, Royal Alexandra Hospital, University of Alberta, Edmonton, AB; 5. Pentavere Research Group, 460 College Street, Toronto, ON M6G 1A1, Canada; 6. Takeda Canada Inc., Toronto, ON

LB020

Background

Teduglutide is indicated for the treatment of patients with short bowel syndrome with intestinal failure (SBS-IF) who are dependent on parenteral support (PS). This study evaluated longer-term teduglutide effectiveness and safety in Canadian patients diagnosed with SBS-IF dependent on PS using Real-World Evidence.

Results

- 52 patients were included in this study. Baseline demographics are shown in **Table 1**
- At 6 months, weekly PS volume significantly decreased from baseline, p<0.001 **(Table 2)**
- By 24 months, weekly PS volume further decreased from baseline, p=0.003 **(Table 2)**
- By 24 months, the proportion of patients who achieved ≥20% reduction in weekly PS was 66.7% **(Figure 1)**
- Of all 52 included patients, 27% achieved independence from PS over the study period
- Adverse events (relatedness to teduglutide undetermined) were reported in 51 (98%) patients (83% were reported as serious in the PSP) during the study period, the 3 most common were weight changes, diarrhoea, and fatigue **(Table 3)**

Method

- This was an observational, retrospective cohort study, using data from the national Canadian Takeda patient support program, and included adults with SBS-IF
- Data including patient characteristics, disease history, teduglutide use and safety were collected 6 months before teduglutide initiation and from initiation to Dec-01-2023, death, or loss of follow-up
- Descriptive statistics characterized the study population and reported adverse events
- Comparisons of continuous variables at pre-defined timepoints with baseline were assessed using Wilcoxon signed-rank tests. Statistical significance was set at p<0.05

Table 1: Baseline clinical and demographic characteristics

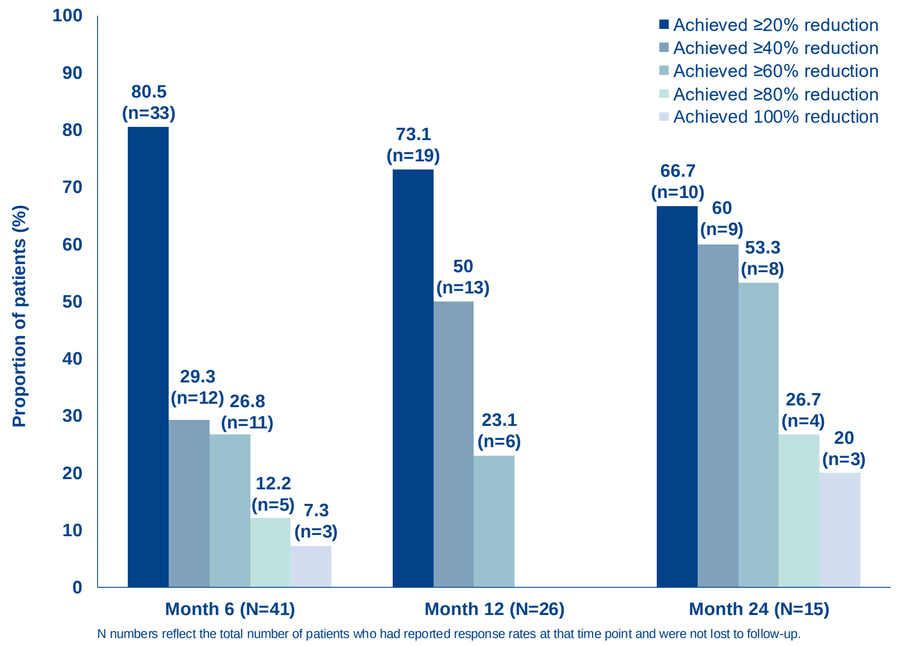
	Overall (N=52)
Age at teduglutide initiation, years	
Median (range)	54.00 (22.00–81.00)
Patient sex	
Female	31 (60%)
Male	21 (40%)
Weight at teduglutide initiation, kg	
Median (range)	65.00 (39.20–109.80)
Missing	3
Duration of SBS-IF before teduglutide initiation, years	
Median (range)	9.98 (0.72–36.16)
Etiology of SBS-IF	
Advanced arterial disease	1 (2%)
Blood clot	8 (15%)
Cancer	2 (4%)
Congenital anomaly	1 (2%)
Crohn's disease	26 (50%)
Ischemic bowel	1 (2%)
Malrotation	2 (4%)
Motility disorder	1 (2%)
Other	1 (2%)
Severe bowel obstruction	2 (4%)
Surgical complication	3 (6%)
Trauma	1 (2%)
Ulcerative colitis	3 (6%)

Table 2: Changes from baseline in PS volume (mL)

	6-month post index date (N=41)	12-month post index date (N=26)	24-month post index date (N=15)
Median (range) percentage reduction from baseline in PS volume (mL)	28.1% (-82.9–100.0)	38.5% (-128.6–77.6)	64.0% (-45.8–100.0)
Median (range) absolute reduction from baseline in PS volume (mL)	3,900 (-6,960–26,784)	4,170 (-14,500–18,000)	6,650 (-4,400– 26,850)
p-value	**<0.001**	**0.013**	**0.003**

N numbers reflect the total number of patients who had reported PS volume at that time point and were not lost to follow-up.

Figure 1: Proportion of patients achieving response rates based on weekly PS volume (mL)



N numbers reflect the total number of patients who had reported response rates at that time point and were not lost to follow-up.

Table 3: 10 most commonly reported adverse events experienced during the study period

Reported adverse event, n (%)	All patients (N=52)
Weight decreased	30 (58%)
Diarrhoea	29 (56%)
Weight increased	22 (42%)
Fatigue	20 (38%)
Product dose omission issue	20 (38%)
Abdominal pain	19 (37%)
Dehydration	19 (37%)
Muscle spasms	18 (35%)
Pain	16 (31%)
Nausea	16 (31%)

Summary/Highlights

Patients showed significant decreases in PS volumes after initiating teduglutide, with no unexpected safety findings. This study demonstrates real-world, longer-term effectiveness of teduglutide in Canadian patients with SBS-IF, and the utility of close long-term follow-up of patients. Thes findings compliment previous clinical trials, and real-world studies.

ESPEN
The European Society for Clinical Nutrition and Metabolism

46th ESPEN Congress
on Clinical Nutrition & Metabolism
Milan, Italy • 7-10 September 2024
CLINICAL NUTRITION : *"THE"* TRANSVERSAL SCIENCE

Disclosures

Funding of this study is from Takeda Canada Inc. Medical writing support was provided by Ruth Moulson of Pentavere Research Group, paid by Takeda Canada Inc. JPA: honorarium from Takeda for speaker and advisory board; research support from Zealand pharmaceutical and OMS Inc. DCD: Dane Christina Daoud has received a sponsorship grant from Shire (Takeda) to pursue a fellowship in intestinal failure; MR: reports speaker fees and grant funding from Lupin, Takeda, Pfizer, Janssen, and Freseni us Kabi; LD and JHC were employees of Takeda Canada Inc. and owns stock/stock options in Takeda at the time of this study; MN and JW were employees at Pentavere Research Group Inc, Toronto, ON, Canada at the time of this study; JJ and LG has no relevant COIs to declare.

Contact information

Corresponding author:
J. P. Allard;
Toronto General Hospital,
University Health Network, Toronto