A Novel Patient-Centered Real-World Evidence Study Designed to Better Understand Short Bowel Syndrome Using Longitudinal Data in the United States

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Background

Short Bowel Syndrome (SBS) is a rare, chronic and debilitating condition that can be defined based upon intestinal dysfunction, i.e. the presence of significant malabsorption of both macro- and micro-nutrients. Individuals with SBS will likely require nutritional therapy and fluid supplementation. SBS in adults usually results from surgical resection of the small intestine for Crohn's disease, trauma, malignancy, radiation, or mesenteric ischemia. Patients with SBS are at risk for several complications. These complications may result from the underlying disease, altered bowel anatomy, and physiology, or its treatment, including the need for parenteral nutrition and the use of a central venous catheter. Evidence is limited with the real-world patient population.

Objectives

The aim of the study is to better understand patient demographics, diagnostic journey, healthcare resource utilization (HCRU) and treatment patterns of patients in the Inspire SBS cohort using primarily medical claims and user-generated contents from the Inspire online community platform.

Methods

Data

- A retrospective study using data from the Inspire Integrated Analytical Database (IIAD), which links Inspire member data with medical and pharmacy claims through HIPAA-compliant tokenization

Study Population

- Inspire members with a combination of ICD-10 diagnosis and CPT/HCPCS codes for post-surgical non-absorption and parenteral infusion from 01/01/2015 to 11/30/2021 were included
- SBS index date was defined as the first service date with a CPT/HCPCS code for parenteral infusion (B4168, B4197, B5000, E0779, B4220, B5100, S9367, S9377, B4180, B4199, B9004, B4185, B4189, B4222, B4224, B5200, B9999, B4216, C8957, B4193, B9006, S9366, B4172, B4178, E0791, S9368, S9375, S9373, S9374, S9376, B4164, B4176, S9364, S9365) that occurs on/after a claim with an ICD-10 code for post-surgical non-absorption (K90.89, K90.9, K91.2)

Analysis

- Baseline patient characteristics and all-cause and SBS-related HCRU were evaluated
- Analysis was performed using descriptive statistics and conducted in R. Median and IQR are presented for continuous variables. Count and percentages are presented for categorical variables.

Results

Patient characteristics

- A total of 165 SBS patients were identified
- The median age at diagnosis was 52 and 79% of patients were female
- Median followup time was 51 months from index date
- A small proportion of the cohort had a previous diagnosis of Crohn's disease (16%) or ulcerative colitis (4%)

Treatment characteristics and Healthcare Resource Utilization

- 84% of the cohort had ≥250 claims from a median of 26 care sites across 44 providers
- The median number of hospitalizations after SBS diagnosis was 4
- Patients often received other treatments with their parenteral nutrition infusion such as meloxicam
- The 5 most common admitting diagnoses were K91.2 (Postsurgical malabsorption), E43 (Unspecified severe protein-calorie malnutrition), N17.9 (Acute kidney failure, unspecified), K31.84 (Gastroparesis) and E83.42 (Hypomagnesemia)
- Patients continued to receive parenteral nutrition at least 1 year after index SBS diagnosis

Healthcare Cost after Index SBS Diagnosis

- In a subset of patients with data on remitted claims (n = 94), median charge amount for all claims within 1 year of SBS diagnosis was $62,682
- Median charge amount per week per claim for parenteral nutrition was $7,000 while median payer was $2,513.27
- Patients may have high out-of-pocket expenses for parenteral nutrition

Inspire platform User Generated Content

- The 5 most common topics viewed on Inspire among the cohort include: GI tract, Stomach, Feeding tube, Nausea and Small intestine
- Post snippets from Inspire's online platform showed that SBS members are concerned about out-of-pocket costs and aspects of TPN that will affect their everyday life (e.g. traveling)

Figure 3. Post snippets on Inspire from SBS Patients

Conclusions

This study characterized a cohort of SBS patients on the Inspire platform, linking patient voice with medical and pharmacy claims. SBS patients in this ongoing retrospective analysis had a median of over 4 years of healthcare visit data since diagnosis and substantial healthcare resource utilization. Use of parenteral nutrition continues at least 1 year post SBS diagnosis, with a potential high out-of-pocket cost for patients. Patient sentiment on Inspire indicate that SBS and parenteral nutrition have a major financial impact and affect patient quality of life.

Limitations

Medical and pharmacy claims may not provide a patient's complete medical journey as there may be gaps in insurance coverage. Adding EHR and other data sources (e.g. labs, PRO, etc.) can further enhance the understanding of the patient journey. Findings from this study may not be generalizable to the broader SBS population.

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Table 1. Patient characteristics

Variable	All Patients (N = 165)
Age at diagnosis (cont.)	52 (42, 64)
Age at dx (cat.)	
18 - 34	20 (12%)
35 - 44	33 (20%)
45 - 54	46 (28%)
55 - 65	33 (20%)
65+	33 (20%)
Gender	
Female	131 (79%)
Male	34 (21%)
Region	
Midwest	17 (10%)
Northeast	13 (8%)
South	41 (25%)
West	11 (7%)
Unknown	83 (50%)
Top 5 Inspire Communities[1]	
Oley Foundation	81 (49%)
AGMD GI Motility Disorders	32 (19%)
Ostomy	30 (18%)
Short Bowel Syndrome Foundation	21 (13%)
Digestive System Disorders	15 (9%)
Previous related diagnosis	
Ulcerative colitis	6 (4%)
Crohn's disease	27 (16%)
Followup time from SBS dx (months)	51 (25, 79)

[1] Patients may join more than one community

Table 2. Healthcare resource utilization

Variable	All Patients (N = 165)
Number of claims per patient (cont.)	807 (397, 1,334)
Number of claims per patient (cat.)	
1 - 49	0 (0%)
50 - 99	8 (4.8%)
100 - 249	19 (12%)
250 - 499	28 (17%)
500+	110 (67%)
Time between first and last claim (months)	92 (79, 98)
No. of distinct facilities	26 (15, 43)
No. of distinct providers	44 (24, 82)
No. of hospitalizations after SBS dx	4 (2, 9)
No of ER visits after SBS dx	2 (0, 8)
Received home health services for K91.2 or E43	29 (18%)

Figure 1. Use of parenteral nutrition after SBS

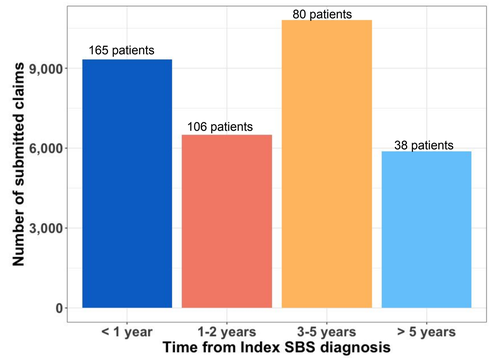


Table 3. Other procedures associated with a parenteral nutrition claim

Procedure	All Patients (N = 165)
J3490 (Meloxicam Injection)	52 patients, 3668 claims
J1955 (Injection, levocarnitine, per 1 gm)	13 patients, 3285 claims
S0028 (Injection, famotidine, 20 mg)	36 patients, 2746 claims
J1642 (injection, heparin sodium, (heparin lock flush), per 10 units)	16 patients, 1035 claims
J1200 (Injection, diphenhydramine HCl, up to 50 mg)	8 patients, 1002 claims

Figure 2a. All-cause healthcare cost (per patient) within 1 year of index SBS diagnosis[1]

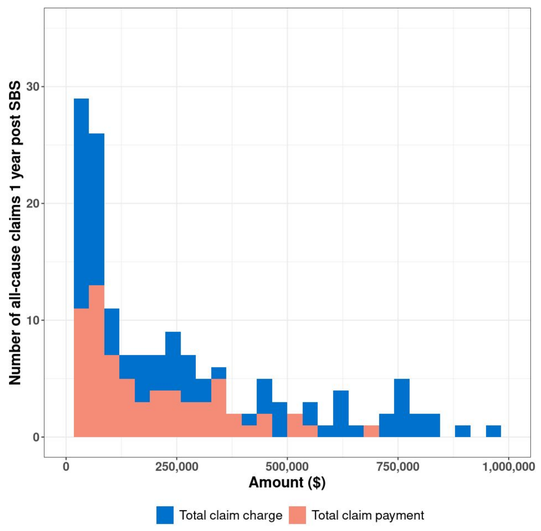
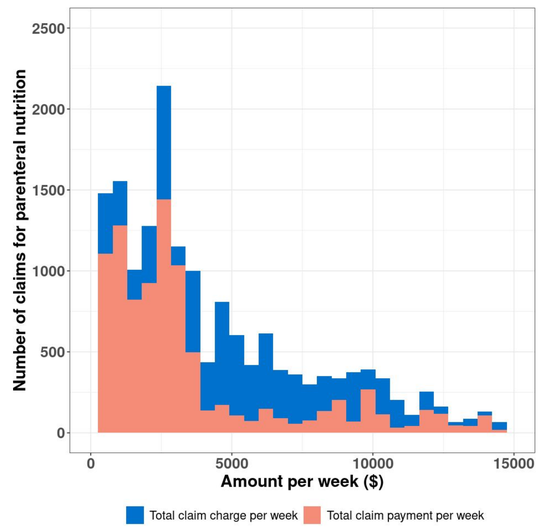


Figure 2b. Cost of parenteral nutrition (per week) after index SBS diagnosis[1]



[1] Extreme outliers are removed from figures

Table 4. Healthcare Costs after index SBS diagnosis

	Claim Charges	Claim Payments
Claims per home health services related to K91.2 or E43 after SBS dx	$325 ($250, $375)[1]	$211 ($152, $223)[1]
Claims per ER visit after SBS dx	$3,635 ($2,397, $5,145)[2]	$1,520 ($706, $2,412)[2]
Claims per patient, for all claims within 1-year of SBS dx	$62,682 ($9,066, $431,409)	$15,041 ($3,570, $138,024)
Cost per week, for all parenteral nutrition claims after SBS dx	$7,000 ($3,910.91, $21,866.88)[3]	$2,513.27 ($1,279, $5,194.00)[3]

[1] n = 11 patients had at least 1 remitted claim for home health services
[2] n = 22 patients had at least 1 remitted claim for an ER visit
[3] n = 94 patients had at least 1 remitted claim for parenteral nutrition