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Evaluation of Fecal Microbiota, Live-jslm by Standard of Care Antibiotic Washout Period for the Prevention of Recurrent *Clostridioides difficile* Infection

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Key Findings

- This real-world study demonstrated the effectiveness of fecal microbiota, live-jslm (RBL) in prevention of rCDI despite being administered beyond 72 hours after SoC antibiotic washout.
- The two groups were similar in baseline demographics and characteristics.
- The group receiving RBL >3 days after SoC antibiotic washout had fewer recurrences but represented a small cohort.
- Additional study would be warranted to further understand challenges with timely administration of RBL.

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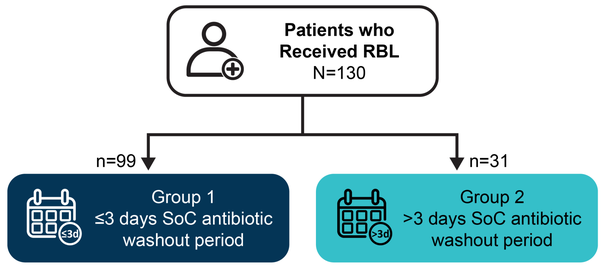
Introduction

- Fecal microbiota, live-jslm (RBL) is the first-in-class microbiome-based therapy approved by the FDA in November 2022 for the prevention of recurrence of *Clostridioides difficile* infection (rCDI) in adults.
- This rectally-administered, pre-packaged single dose microbiota suspension has been proven to be safe and efficacious in clinical trials.
- RBL is indicated to be administered after 24-72 hours of washout from standard of care (SoC) antibiotic for CDI infection. Various factors contribute to timely administration of RBL in real-world practice.
- The objective of this study was to evaluate the patient characteristics and treatment outcomes of RBL-treated patients, comparing those receiving RBL either 24-72 hours or >72 hours post-SoC washout period.

Methods

- A multicenter cohort study was conducted of patients ≥18 years old who received RBL in Infectious Disease or Gastroenterology physician offices across the US between February 2023 to April 2025.
- Patients were included who received RBL after SoC antibiotic treatment for rCDI and divided into two groups based on SoC antibiotic washout period: 24-72 hours (≤3 days) from SoC completion (Group 1) and >72 hours up to 42 days (>3 days) following SoC completion (Group 2).
- Data was collected from centralized medical records for each group including patient demographics, comorbidities, number of prior CDI episodes, prior CDI treatment, rCDI risk factors, and CDI treatment for current episode, including standard of care (SoC) antibiotics and washout period.
- Recurrence was evaluated by group and defined as 3 or more liquid bowel movements within 24 hours that required CDI-related therapy through 8 weeks post-RBL administration. Treatment success was defined as absence of recurrence at 8 weeks.
- rCDI risk factors were assessed by group and included age ≥65 years, use of gastric acid suppressant therapy[a], non-CDI antibiotic use within 4 weeks prior to current CDI episode, and a compromised immune system[b]. Other factors contributing to rCDI were evaluated by group and included inflammatory bowel disease, CDI with severe presentation[c], or chronic renal disease.
- Continuous data were reported as means with standard deviations (SD) or medians with interquartile ranges (IQR), and categorical data as counts and percentages. Pearson's Chi-Square test was used to test for statistical significance. P values <0.05 were considered statistically significant.

Study Design



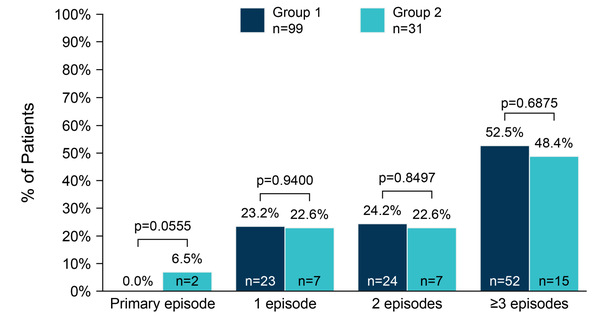
Patient Characteristics

Variable	All Patients (N=130)	Group 1 (n=99)	Group 2 (n=31)	P-value
Age, median (IQR) years	72.0 (62.0-80.0)	72.0 (63.5-80.0)	71.0 (61.0-81.0)	0.6735
Female, n (%)	95 (73.1)	69 (69.7)	26 (83.9)	0.8240
Charlson comorbidity index, median (IQR)	4.0 (3.0-6.0)	4.0 (3.0-6.0)	4.0 (2.0-6.0)	0.8320
Prior CDI episodes, not including current				
No. of prior CDI episodes, median (IQR)	3 (2-3)	3 (2-3)	2 (1-3)	0.8240
0 episodes, n (%)	2 (1.5)	0 (0.0)	2 (6.5)	0.0555
1 episode, n (%)	30 (23.1)	23 (23.2)	7 (22.6)	0.9400
2 episodes, n (%)	31 (23.8)	24 (24.2)	7 (22.6)	0.8497
≥3 episodes, n (%)	67 (51.5)	52 (52.5)	15 (48.4)	0.6875
No. of rCDI risk factors, n (%)				
0	14 (10.8)	10 (10.1)	4 (12.9)	0.6605
1	60 (46.2)	48 (48.5)	12 (38.7)	0.3407
2	37 (28.5)	27 (27.3)	10 (32.3)	0.5914
≥3	19 (14.6)	14 (14.1)	5 (16.1)	0.4939
rCDI risk factors, n (%)				
Age ≥65 years	92 (70.8)	73 (73.7)	19 (61.3)	0.2253
Concurrent gastric acid suppressant use[a]	55 (42.3)	37 (37.4)	18 (58.1)	**0.0419**
Immunocompromised[b]	25 (19.2)	19 (19.2)	6 (19.4)	0.9840
Non-CDI antibiotic use within 4 weeks prior to episode	22 (16.9)	18 (18.2)	4 (12.9)	0.4940
Other characteristics, n (%)				
Current CDI with severe presentation[c]	13 (10.0)	11 (11.1)	2 (6.5)	0.4505
Hospitalization within 4 weeks of current CDI	13 (10.0)	10 (10.1)	3 (9.7)	0.9453
Inflammatory bowel disease	10 (7.7)	7 (7.1)	3 (9.7)	0.6346
Incomplete Retention	7 (5.4)	7 (7.1)	0 (0.0)	0.1962
Days from Soc completion to RBL administration, median (IQR)	**2.0 (2.0-3.0)**	**2.0 (2.0-3.0)**	**9.0 (5.0-18.0)**	**<0.0001**

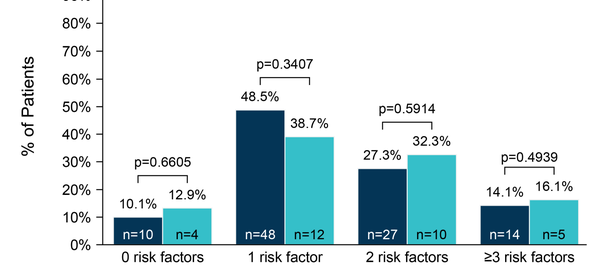
- Reasons for Group 2 treatment >3 days following SoC antibiotic were: prolonged approval process (n=14), scheduling factors (patient, provider, drug procurement) (n=14), and competing medical condition (n=3).

Results

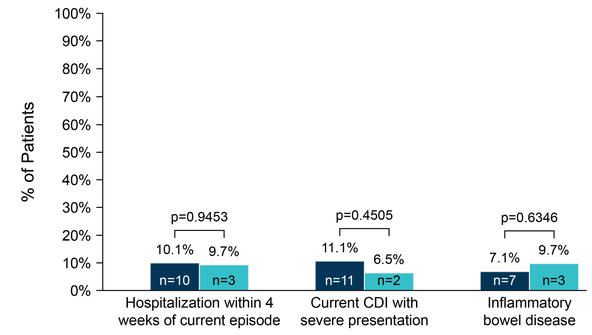
Number of Prior CDI Episodes by Group



Number of rCDI Risk Factors by Group

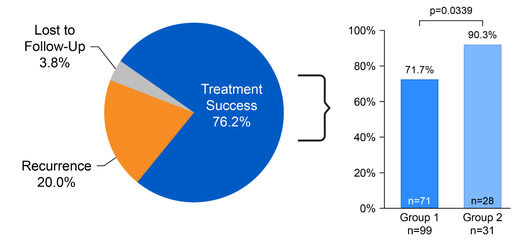


Other rCDI Contributing Factors by Group



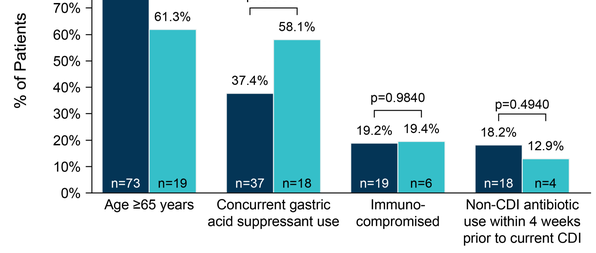
Treatment Outcomes

Treatment Outcomes at 8 Weeks by Group



- Recurrence by group was 25 (25.3%) in Group 1 and 1 (3.2%) in Group 2 (p=0.0075).
- 6 out of 7 patients with incomplete retention recurred at 8 weeks.

Type of rCDI Risk Factor by Group



DISCUSSION

This real-world study compares the patient characteristics and treatment outcomes of rCDI patients treated with RBL with a SoC antibiotic washout period of ≤3 days or >3 days.

- The groups were similar in age, Charlson comorbidity index, sex, prior CDI history, and other rCDI contributing factors.
- Among rCDI risk factors, only gastric acid suppressant use was significantly different between the two groups.
- Fewer patients in Group 1 reached treatment success at 8 weeks compared with Group 2. Of note, all patients with incomplete retention were in Group 1, with 6 of 7 patients recurring at 8 weeks.
- These data suggest that RBL continues to be effective in preventing recurrences despite being administered beyond 72 hours after SoC antibiotic washout.

Abbreviations and Definitions

Abbreviations: ABX, antibiotic; CDI, *Clostridioides difficile* infection; IQR, interquartile range; RBL, fecal microbiota, live-jslm; rCDI, recurrent *Clostridioides difficile* infection; SD, standard deviation; SoC, standard of care

Definitions: [a]Proton pump inhibitor and/or histamine-2 receptor antagonist
[b]Due to immunosuppressive medication or underlying disease (immune deficiency, solid organ or hematopoietic stem cell transplant, absolute neutrophil cell count <500 cells/mL)
[c]Defined by any of the following: albumin ≤3.0 g/dl, serum creatinine ≥1.5 times above baseline, hypotension or shock, intensive care unit stay related to CDI, ileus, serum lactate >5 mmol/L, toxic megacolon or colectomy related to CDI, white blood cell count ≥15,000 cells/mL.

References

1. Rebyota (fecal microbiota, live - jslm) [package insert]. Roseville, MN: Ferring Pharmaceuticals; 2022.
2. Dubberke ER, et al. Infect Dis Ther. 2023; 12:703–710.
3. Khanna S, et al. Drugs. 2022; 82:1527–1538.

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