

# Real-World Effectiveness of Fecal Microbiota, live-jslm for the Prevention of Recurrent *Clostridioides difficile* Infection

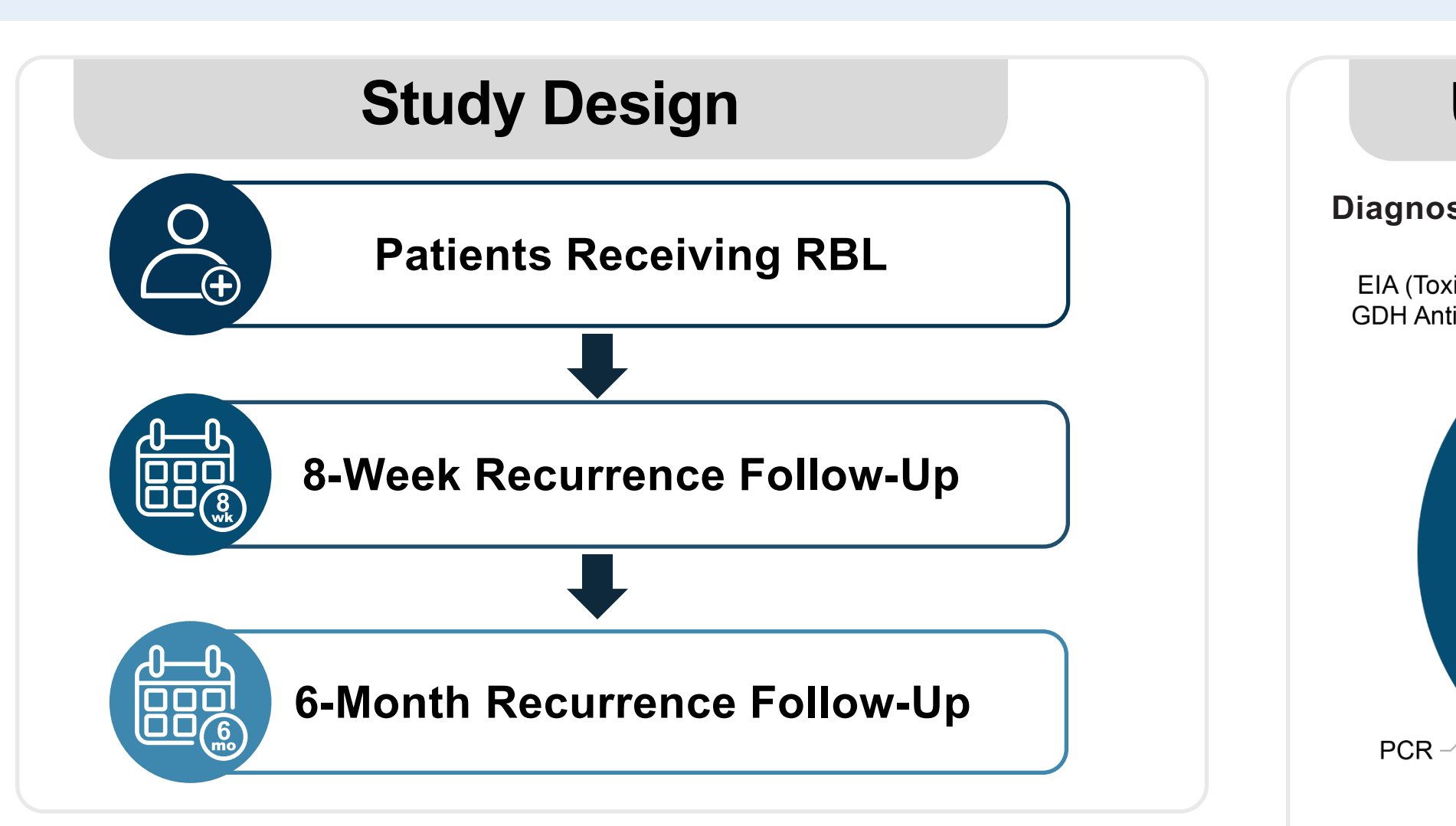
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## Key Findings

- RBL demonstrated high efficacy at 8 weeks with the large majority of patients recurrence free at 6 months.
- Recurrence was most commonly seen in the first month following treatment.
- RBL was safe and well tolerated.
- Results are comparable to the data reported in the PUNCH CD3 trial despite a more comorbid population.<sup>2,3</sup>

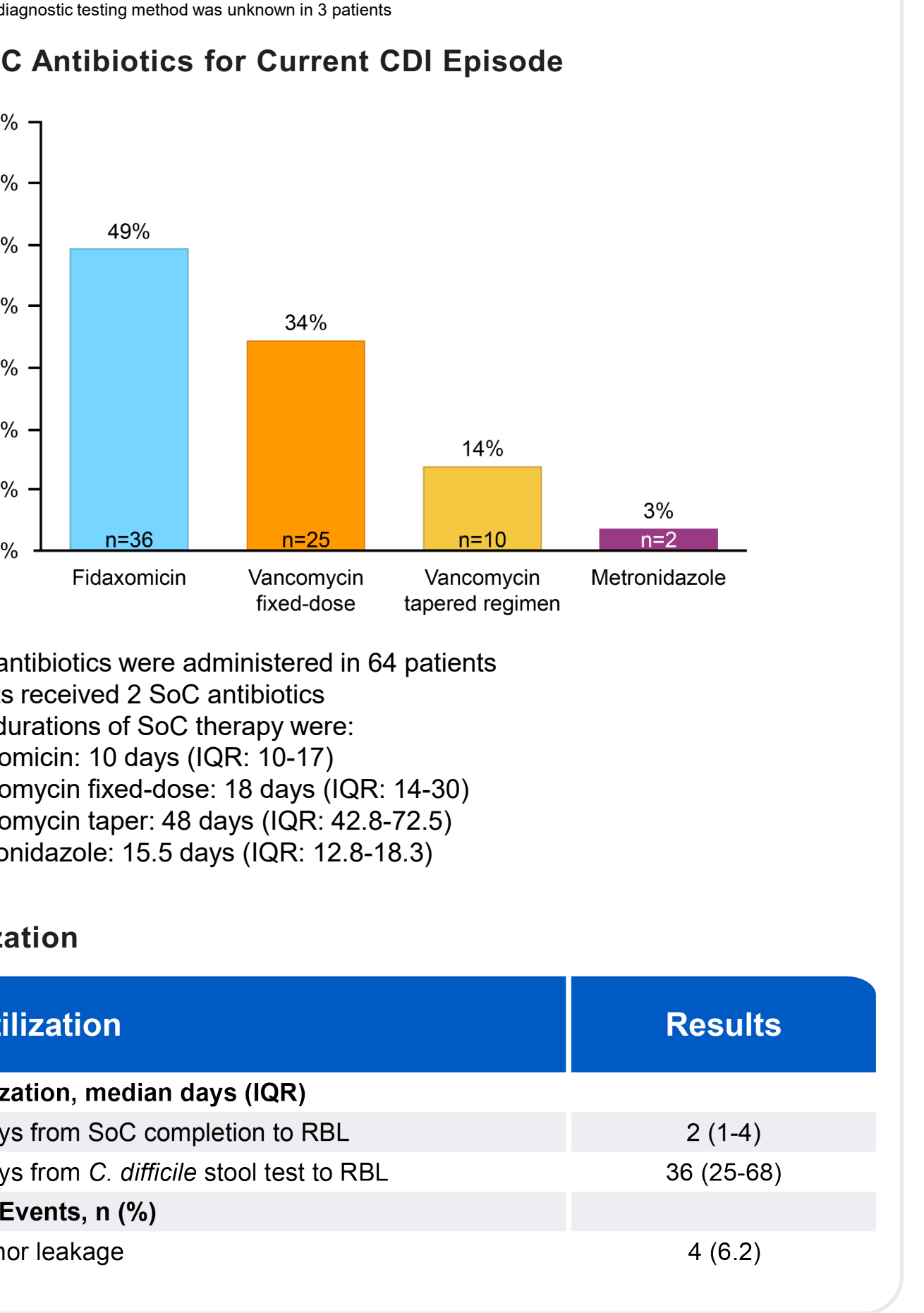
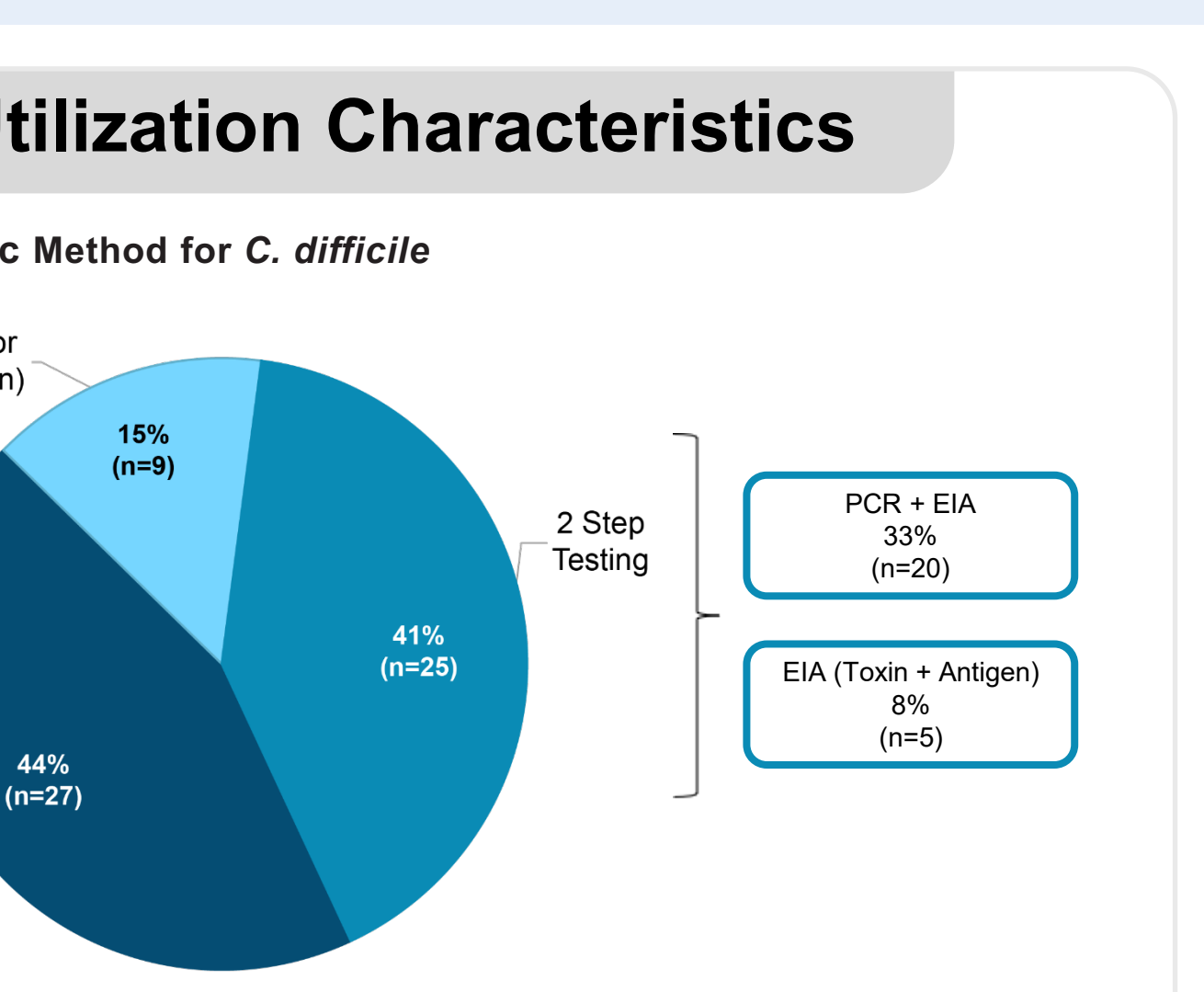
## Background



### Patient Characteristics

Characteristic	Results (N=64)
Age, median (IQR) years	75 (64.8-82.3)
Female, n (%)	42 (65.6)
Hospitalization within 4 weeks of current CDI, n (%)	4 (6.3)
Charlson comorbidity index, median (IQR)	4.5 (3.0-7.0)
<b>CDI history</b>	
Number of prior CDI episodes, not including current, median (IQR)	3 (1-3)
0 episodes	1 (1.6)
1 episode	19 (29.7)
2 episodes, n (%)	10 (15.6)
≥3 episodes, n (%)	34 (53.1)
<b>Number of rCDI risk factors, n (%)</b>	
0	5 (7.8)
1	21 (32.8)
2	22 (34.4)
≥3	16 (25.0)
<b>rCDI risk factors, n (%)</b>	
Age ≥65 years	48 (75.0)
Concurrent gastric acid suppressant use <sup>a</sup>	38 (59.4)
Immunocompromised <sup>b</sup>	16 (25.0)
Non-CDI antibiotic use within 4 weeks prior to current CDI	13 (20.3)
<b>Other characteristics, n (%)</b>	
Chronic renal disease	11 (17.2)
Current CDI with severe presentation <sup>c</sup>	7 (10.9)
Inflammatory bowel disease	6 (9.4)
Bezlotoxumab therapy with prior episode	8 (12.5)
Bezlotoxumab therapy with current episode	7 (10.9)

## Methods

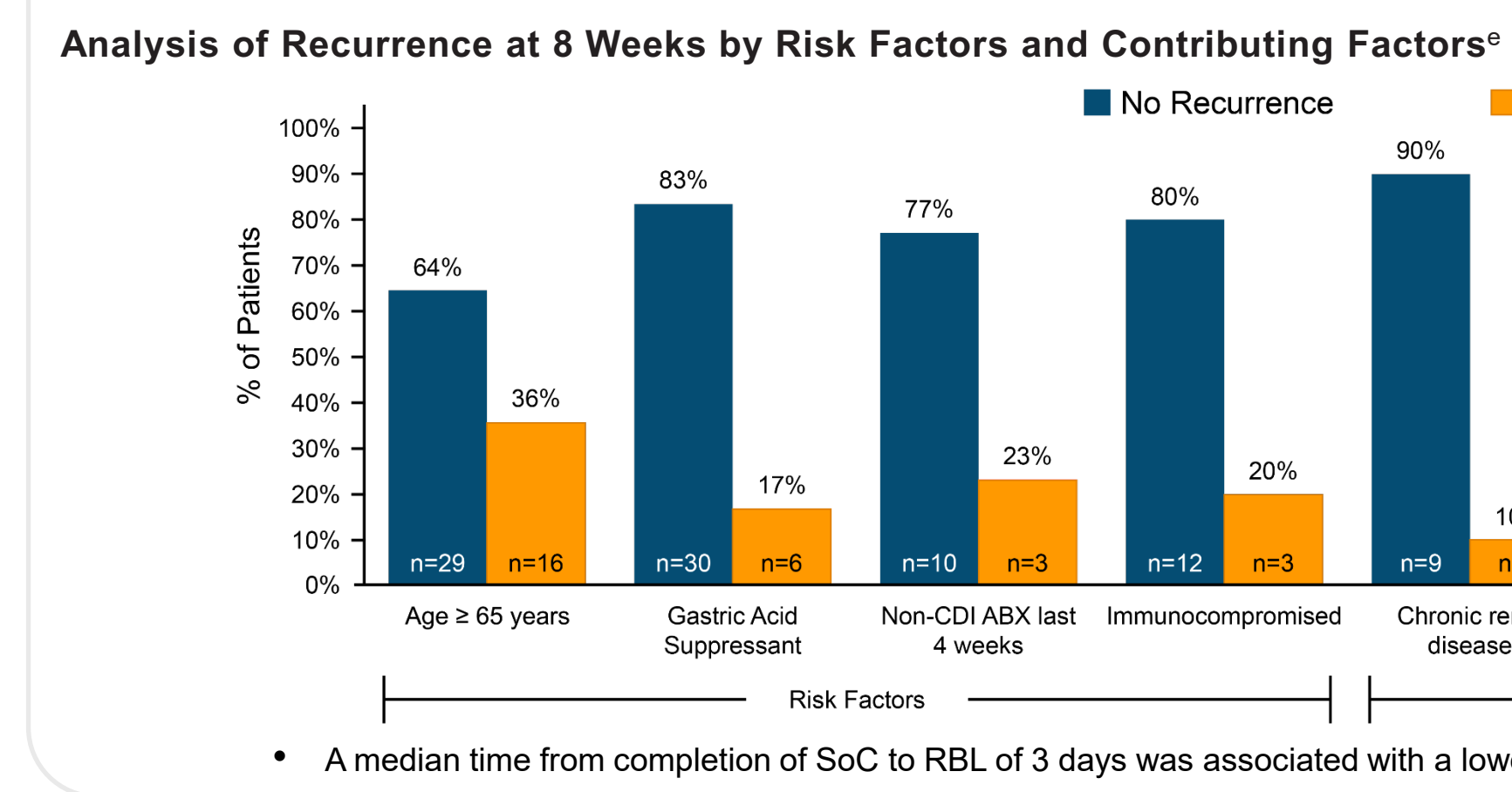


## Recurrence

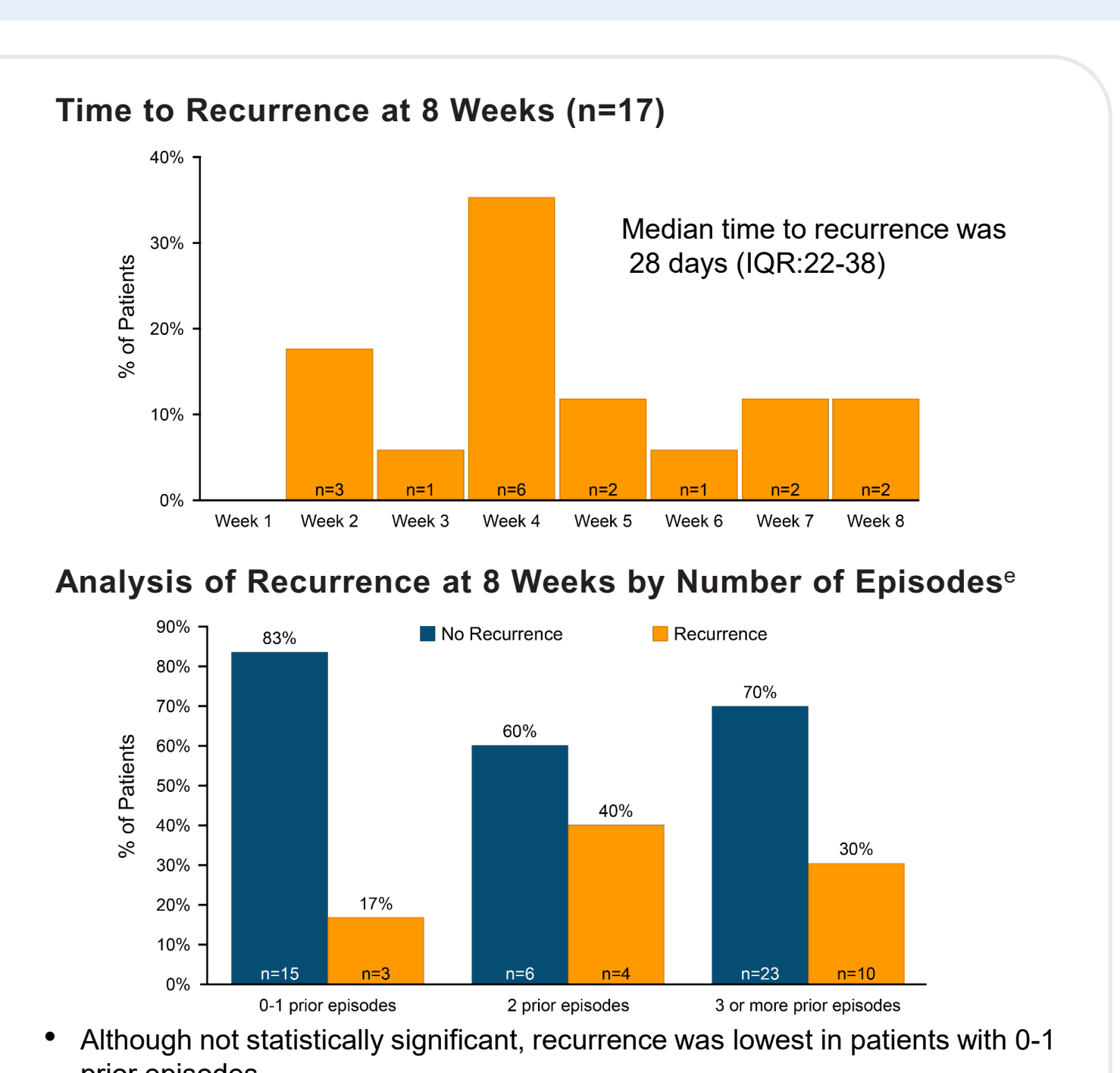
Evaluation Time Point	Total Population (includes lost to follow-up)			
	No Recurrence		Recurrence	
	n/N	%	n/N	%
8 Weeks	44/64	69%	17/64	27%
6 Months	30/42	71%	4/42	10%

Evaluation Time Point	Evaluable Population (excludes lost to follow-up) <sup>d</sup>			
	No Recurrence		Recurrence	
	n/N	%	n/N	%
8 Weeks	44/61	72%	17/61	28%
6 Months	30/34	88%	4/34	12%



## Recurrence



## DISCUSSION

This study provides real-world data on the effectiveness of RBL in preventing rCDI in an outpatient setting.

- Over 90% of patients had 1 or more rCDI risk factor, with age ≥65 years being most common.
- More than half of patients had ≥3 prior CDI episodes.

Among those with evaluable data, treatment success was observed in 72% of patients, with sustained response of 88% at 6 months.

- The highest number of recurrences occurred at 4 weeks post-RBL administration.
- The adverse event rate was low with only minor leakage reported in 4 patients.
- Limitations of the study include lack of testing to confirm rCDI following RBL administration, potentially leading to higher reported cases of recurrences.

## Abbreviations and Definitions

Abbreviations: ABX, antibiotic; CDI, *Clostridioides difficile* infection; EIA, enzyme immunoassay; FMT, fecal microbiota transplant; GDH, glutamate dehydrogenase; IQR, interquartile range; PCR, polymerase chain reaction; RBL, fecal microbiota, live-jslm; rCDI, recurrent *Clostridioides difficile* infection; SD, standard deviation; SoC, standard of care

Definitions: <sup>a</sup>Proton pump inhibitor and/or histamine-2 receptor antagonist; <sup>b</sup>Due to immunosuppressive medication or underlying disease (immune deficiency, solid organ or hematopoietic stem cell transplant, absolute neutrophil cell count <500 cells/mL); <sup>c</sup>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; <sup>d</sup>8-Week Follow-Up: Non-evaluable patients included lost to follow up (n=1), deceased unrelated to CDI (n=2); 6-Month Follow-Up: Non-evaluable patients included lost to follow up (n=4), deceased unrelated to CDI (n=4); <sup>e</sup>Results shown for the evaluable population.

## 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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