There is No Association Between Patient Outcomes and Demographics in an Open Label Safety and Efficacy Study of RBX2660, a Microbiota-Based Drug for Recurrent *Clostridium difficile* Infection

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Introduction

Microbiota therapy is gaining acceptance to prevent recurrent *Clostridium difficile* infection (rCDI) in multi-recurrent patients. Recent microbiota-based therapy trials have suggested that treatment outcomes may be subject to demographic differences. However, a recent double-blind, placebo-controlled Phase 2B trial of RBX2660, a standardized microbiota-based drug, demonstrated no association between demographics and efficacy to prevent rCDI. Herein we evaluated data from a Phase 2 open-label trial of RBX2660 to determine whether rCDI prevention differed in relationship to age, gender, or geographic location.

Methods

This prospective, multicenter, open-label Phase 2 study enrolled patients who had experienced either ≥2 CDI recurrences following ≥2 courses of standard-of-care antibiotic therapy or ≥2 episodes of severe CDI that required hospitalization. Patients received up to 2 doses of RBX2660 (a microbiota-based drug manufactured from live human-derived microbes) delivered via enema with doses 7 days apart. Efficacy was defined as no CDI recurrence through 56 days after completion of treatment. Efficacy rates were compared between RBX2660-treated patients and a matched set of antibiotic-treated historical controls. Subjects in the historical control arm met all inclusion criteria applicable to subjects treated with RBX2660 and were analyzed as if with the antibiotic treated as placebo. Demographic information was collected at time of enrolment. For this interim analysis, logistic regression was used to determine probability of demographic impact on successful rCDI prevention.

Results

A total of 138 RBX2660 and 110 historical control subjects were included from 31 and 4 centers, respectively, in the United States and Canada. Efficacy for RBX2660 to prevent rCDI was significantly higher than CDI-free rates in the historical control group ($p < 0.001$). Demographics, clinical variables and patient outcomes (Table 1) were fit to a logistic regression model. Treatment success was not dependent on age, gender, or geographic site of administration ($p>0.05$). Treatment was the only factor that had a significant effect on outcome ($p < 0.05$).

Discussion

Patient age, gender, and geographic location did not have a statistically significant impact on rCDI patient outcome in this open-label study of RBX2660, extending previous findings from a randomized controlled trial.

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TABLE 1.

		OUTCOME	
		Success	Fail
TREATMENT	RBX2660	110	28
	Historical Control	55	55
AGE (years)	under 65	73	26
	65 +	92	57
GENDER	Female	114	51
	Male	51	32
REGION	Canada	10	5
	East	29	16
	Midwest	63	42
	South	40	4
	West	23	16